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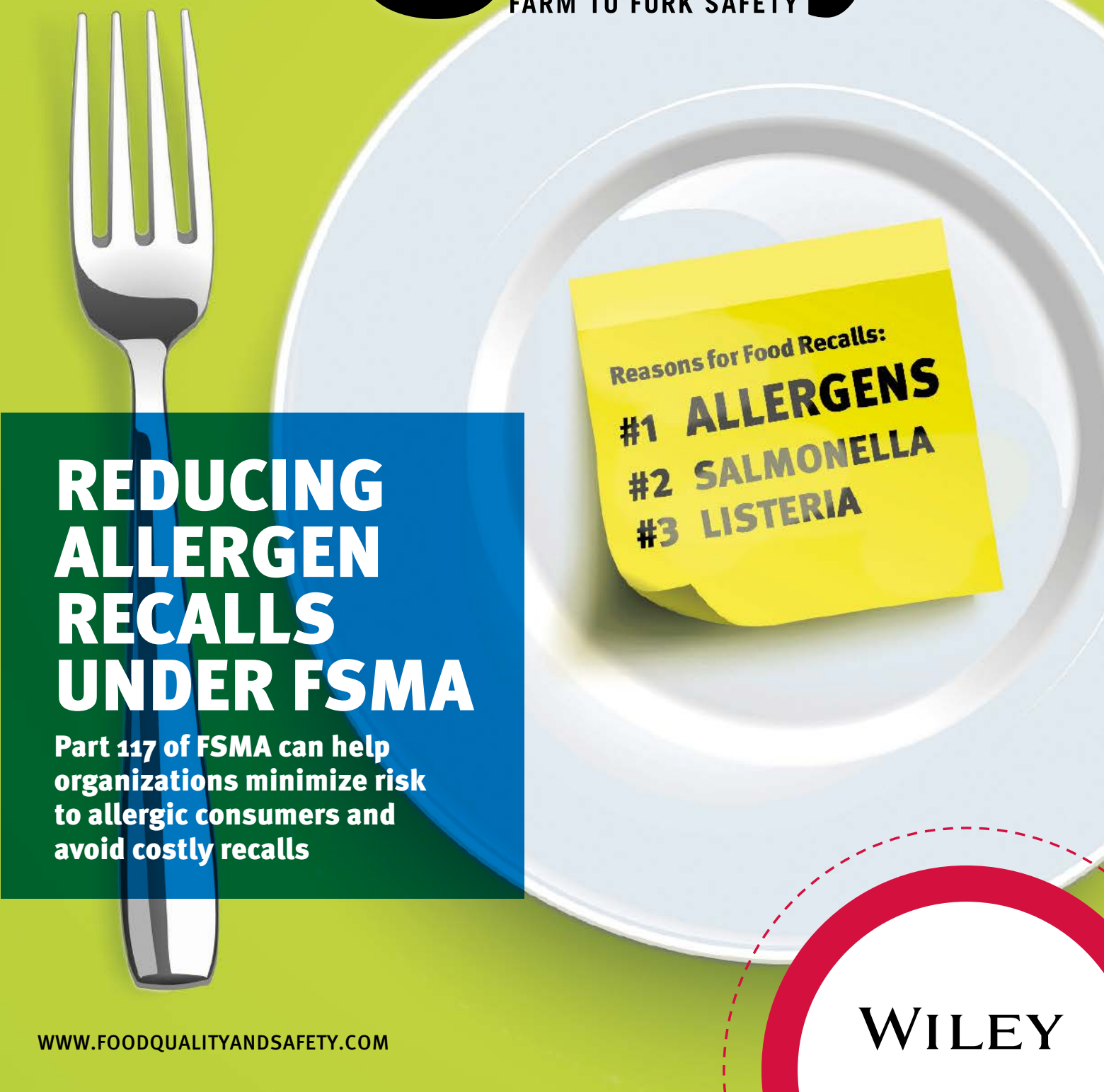
DECEMBER 2016 / JANUARY 2017

Food Quality & Safety

FARM TO FORK SAFETY



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Part 117 of FSMA can help organizations minimize risk to allergic consumers and avoid costly recalls

BY CORNELIUS HUGO

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From The Editor

Ever since Donald Trump was elected the 45th president of the U.S. on November 9, he has been busy recruiting for his administration—leaving many to wonder if he and his team will follow through on all the Trump campaign promises. One of those promises of particular importance to the food industry was his push for less regulations.

While food safety didn't play a huge role in his presidential campaign, Trump did create some unease in the industry when a fact sheet was posted online in September, and later deleted, in which the Trump campaign highlighted a number of "specific regulations to be eliminated." This included what they called the "FDA Food Police" whose rules govern "the soil farmers use, farm and food production hygiene, food packaging, food temperatures, and even what animals may roam which fields and when."

Proposing to do away with these rules certainly raised concerns from industry stakeholders responsible for protecting the public from contaminated food.

However, a president is unable to simply wave his/her hand and totally eliminate a rule. Yet, as reported by CivilEats.com, "executive orders—actions by the president that did not go through a legislative or agency rulemaking process, such as the Executive Order Combatting Antibiotic-Resistant Bacteria—can be easily undone. Also vulnerable to actual undoing are unfinished agency rules and regulations." This means that the business not completed by USDA, FDA, and EPA at the end of the Obama administration will now be passed to Trump and his team to handle.

Although he made his dislike for regulations well known on the campaign trail, it's not clear if regulations concerning food policy will be affected during Trump's term. Regardless, the industry has an obligation to continue its push for food safety initiatives with this new administration—despite political views.

Marian Zboraj
Editor

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FARM TO FORK SAFETY

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NEWS & NOTES

U.S. and Mexico Establish Joint Organic Compliance Committee

USDA Agricultural Marketing Service announces plans to establish a Joint Organic Compliance Committee to enhance cooperation and ensure the integrity of organic products traded between the U.S. and Mexico. Once convened, the committee will establish requirements for the use of import certificates in both countries within six months to provide verification of each shipment of organic products. In addition, the Committee will implement sampling of organic products for chemical residues and will share sampling results with the two countries' regulatory authorities. The committee will further engage with certifiers operating in Mexico by conducting listening sessions to determine any additional training, oversight, or policy guidance needs.

New Association for Food Safety Auditing Professionals

The Association of Food Safety Auditing Professionals will provide a national platform for food safety auditors to engage with all stakeholders in the evolving post-FSMA auditing landscape. This peer support network will work together to enhance the auditor's role and advance the food safety auditing profession. For more information, contact info@afsap.org.

AFSAP
ASSOCIATION OF FOOD SAFETY AUDITING PROFESSIONALS

Have an Idea for a Book on Food Safety?

Wiley is a major international publisher with one of the world's leading programs in food safety and all other aspects of food science and technology. Alongside *Food Quality & Safety* magazine, Wiley publishes some of the major scholarly journals in this subject area as well as a huge range of book titles aimed at industry professionals, students, and researchers. If you have an idea for a new book or another publishing project, please send details to David McDade, executive editor, at dmcdade@wiley.com.

Food Loss and Waste Reduction Approaches

The Consumer Goods Forum (CGF) releases its Food Waste Booklet, a compilation of real-life examples from the CGF members on how they are measuring and reducing food loss and waste. The booklet is the third CGF case study booklet in a series focused on environmental sustainability, along with the CGF Refrigeration Booklet that highlights how members are phasing out HFCs and implementing natural refrigeration alternatives, and the CGF Climate Change Booklet containing examples of how members are making business changes to have a positive impact on the climate with the goal of keeping global temperature rises below 2ºC.

Business Briefs

LRQA is now a member of **Sedex**—the Supplier Ethical Data Exchange, which is a not-for-profit membership organization dedicated to driving improvements in responsible and ethical business practices in global supply chains.

3M joins the Alliance for Advanced Food Sanitation, launched in 2015 by the **University of Nebraska-Lincoln.**

Phenomenex signs a definitive agreement to be acquired by **Danaher**; it will operate as a standalone company, retaining the Phenomenex brand, its personnel, and site locations.

Nelson-Jameson in conjunction with **Dairy Connection** have partnered with France-based **Lallemand Specialty Cultures** to help serve customers in the U.S. Lallemand develops solutions for artisan and specialty cheeses as well as dry fermented meat.

Cascades introduces its new brand identity within its Tissue Group division, Cascades Pro—the culmination of a major brand transformation for the former Away-From-Home division.

Digi International acquires **FreshTemp**, a provider of temperature monitoring and task management solutions for the IoT cold chain market.

FoodLogiQ and **WQS Food Verification** form partnership to pair auditing services with a fully mobile, cloud-based supplier management and traceability platform.

NIFA Awards $4.7 Million for Food Safety Education

USDA's National Institute of Food and Agriculture (NIFA) awarded more than $4.7 million in grants for food safety education, training, and technical assistance projects for producers who are impacted by the new food safety guidelines established by FDA under FSMA. The grants, made available through NIFA's Food Safety Outreach Program, will assist owners and operators of small to mid-sized farms, beginning farmers, socially-disadvantaged farmers, small processors, small fresh fruit and vegetable wholesalers, food hubs, farmers markets, and others. The 2016 awards were made in three categories: Pilot Projects to support the development and implementation of new food safety education and outreach programs in local communities that address the needs of small, specialized audiences; Community Outreach Projects focused on growth and expansion of existing food safety education programs; and Multistate education and training projects to support the implementation of multi-county, statewide, or multi-state food safety education and outreach programs where there are common food safety concerns.

In FDA News...

FDA issues revised food safety standards for state regulatory programs that oversee food facilities that manufacture, process, pack, or hold foods. These regulatory program standards, known as the Manufactured Food Regulatory Program Standards (MFRPS), were first issued by the agency in May 2007. The 2016 updates include newly defined terms, new sections and appendices, as well as updates to the current standards.

The agency also releases final guidance for industry for a voluntary, fee-based program to allow the expedited review and importation of foods into the U.S. from importers with a proven track record of food safety and security. The Voluntary Qualified Importer Program guidance explains how expedited entry provides importers an incentive to adopt a robust system of supply chain management and allows FDA to focus its resources on examining and sampling food imports that are more likely to present a potential risk to public health.

Additionally, FDA announces that Jan. 1, 2020 will be the uniform compliance date for food labeling regulations that are issued in calendar years 2017 and 2018. This action does not change existing requirements for compliance dates contained in final rules published before Jan. 1, 2017.

Washington Report

How Brexit May Complicate U.S. Food Exports

The U.K.'s withdrawal from the EU will have an effect on U.S. trade to all of Europe | BY **TED AGRES**

Barring legal challenges, by March 2017, the U.K. intends to submit a formal resolution to the European Union (EU) to begin a two-year process of withdrawing its membership and establishing new trade and other agreements with the 27 remaining EU member countries, the U.S., and other nations. Food safety experts, economists, and agricultural analysts agree that Brexit will have a major impact on U.S. food exports to the U.K. and Europe. But the specifics are likely to remain uncertain until the process is completed by early 2019.

"It is difficult to say what the implications for businesses will be until more is known about the U.K.'s future relationship with the EU agreed as part of the exit negotiations," says Paul Friedman and Alistair Maughman, attorneys in the London office of the international law firm Morrison & Foerster.

One likely effect, however, will be continued currency fluctuations and economic uncertainty. Immediately after the June 23, 2016 referendum for the U.K. to leave the EU, the British pound sank and global equities plummeted in a record-setting $2 trillion single-day loss amid fears of a worldwide economic collapse. While the situation has since stabilized, a continuing weak British pound will make U.S. products more expensive and affect the competitiveness of U.S. agriculture and food exports to the U.K.

Those exports totaled $2.7 billion in 2014, led by consumer-oriented food and beverage products ($983 million or about 37 percent of the total), according to the USDA's Foreign Agricultural Service. The largest components of this category were wine and beer, tree nuts, prepared food, processed fruit and vegetables, and snack foods.

And while the U.K. remains the leading European market for U.S. goods and services overall, the food and agricultural portions are tiny, with the U.K. accounting for only $1.8 billion or 1.35 percent of America's $133 billion in worldwide agricultural exports in 2015. Eggs and egg-related products were the only category in which the U.K. made the top 10 list for U.S. agricultural products, according to a report from AgriBank, a farm credit bank in St. Paul, Minn., which supports farm associations in 15 mostly Midwest states.

"In the short-term, Brexit will have little impact on the bottom line for most domestic producers," the AgriBank report says. Because the U.K. will remain in the EU for up to two more years, existing trade agreements will remain in effect during that time. The larger question is whether Brexit is an isolated event or represents the start of a larger protectionist trend that spreads across the EU and beyond.

"The thing that could move this from a relatively minor blip to a full-blown crisis is how the geopolitical issues play out," explains Luis Sahmkow, AgriBank's vice president and treasurer. "There are also EU members like the Netherlands and Finland that have fairly high levels of 'Euro skeptic' sentiment, and it remains to be seen if voters in those countries will push for exit referendums," he says. "If so, that will drive even more uncertainty."

Such Brexit-related uncertainty is clearly not good for U.S. food and agricultural producers, which have struggled to increase their EU-related market share. For example, while the U.S. enjoyed a $16-billion global trade surplus in agricultural goods in 2015, it suffered a record $12-billion agricultural trade deficit with the EU.

Some experts are sanguine about Brexit's impact on U.S. food exports. "Brexit will have no impact per se unless the U.K. puts up non-tariff trade barriers at some point down the road," says David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. But others say

that if Brexit goes through, tariffs could rise because trade deals and policies would need to be renegotiated. For U.S. food businesses that use Britain as their gateway to the rest of the EU, this could mean increased costs to gain access to European markets. "There will likely be tariffs to pay for cross-border market access," said Matthew Beesley, head of global equities for Henderson Global Investors. "It is to be negotiated, so we just don't know. This is the uncertainty," he told CNBC.

The indirect effects will matter most, argues Philip Abbott, professor of agricultural economics at Purdue University. "The effects on agricultural trade will be through the exchange rate mechanism and through any negative business cycle effects involving global demand. How big those are depends on whether [Brexit] is a temporary or longer-term situation," says Abbott, who specializes in international trade and agriculture.

Agriculture is generally more dependent on international trade than are other parts of the economy, adds Mike Boehlje, a distinguished professor of agricultural economics at Purdue. "Globalization is important to U.S. agriculture to keep markets open to access," Boehlje says. "These are probably the more important longer-term issues. We don't know what the answers are yet."

Background to Brexit

In the June 2016 referendum, nearly 52 percent of the U.K. residents who voted sided with leaving the EU while 48 percent wanted to remain. The impetus for withdrawal had been brewing for several years, fueled primarily by concerns over large numbers of immigrants entering Britain from other European countries, the nation's ability to make its own laws, and the impact of EU membership on the economy.

In October 2016, Theresa May, Britain's newly appointed prime minister, announced that she would invoke Article 50 of the Treaty on European Union by the end of March 2017, triggering the complex process of withdrawing from the EU by March 2019. However, her decision to do so was quickly challenged in court. In early November, England's High Court ruled that the government requires approval from Parliament to trigger the exit process. "The court does not accept the argument put forward by the government," said Lord Chief Justice John Thomas, England's most senior judge. "We decide that the government does not have power…to give notice pursuant to Article 50 for the U.K. to withdraw from the European Union." The government promptly appealed the case to the Supreme Court, which was scheduled to hear arguments Dec. 5-8, 2016. But the government plans to push ahead. "Our plan remains to invoke Article 50 by the end of March," a spokesperson for May said. "We believe the legal timetable should allow for that."

Despite being in flux, Brexit has already negatively impacted at least one pending international trade agreement. Over the past three years, the Obama administration and EU officials have been negotiating the Transatlantic Trade and Investment Partnership (TTIP) agreement, a bilateral trade and investment deal between the EU and the U.S. intended to boost economic growth by, among other things, eliminating all trade tariffs and reducing "behind the border" non-tariff barriers that impede the flow of food and agricultural products.

But in late September, EU trade ministers announced that it was "unrealistic" to expect TTIP to be finalized by year's end, given the politically uncertain climate surrounding trade deals on both sides of the Atlantic and a new U.S. president who most certainly would want to appoint his or her own trade negotiators.

"If we do not conclude TTIP before the 19th of January [2017], then there would be a natural pause because any American administration has all of these confirmations and Senate hearings and so on," explained Cecilia Malmström, EU trade commissioner, during a meeting of trade ministers in Slovakia in late September. She added that it was too soon to speculate when negotiations might resume.

Brexit's Impact on Food Safety

As the U.K. seeks to negotiate a new relationship with the EU, it is likely to explore various models adopted by other countries. Using the Norwegian model, for example, the U.K. would continue to have access to the EU single market under the European Economic Area and the European Free Trade Area agreements, but would be required to make financial contributions to the EU without having any right to participate in rulemaking.

Or under the Swiss model, the U.K. would enter into various bilateral agreements with the EU but would also be bound by EU rules, including those that are unpopular with Brexit supporters, particularly the free movements of people. The U.K. could also establish a comprehensive free-trade agreement with the EU, but this is likely to be time-consuming; it took South Korea and Canada four and five years, respectively, to conclude their free-trade agreements.

"It may be that what is eventually agreed is a bespoke arrangement between the U.K. and EU, which borrows from several of the models mentioned above, possibly involving some form of 'associate' membership status for the U.K.," explained Friedman and Maughman in a Morrison & Foerster briefing document.

Regardless of the final agreement or agreements that the U.K. establishes with the EU or with separate countries, food safety laws and regulations will likely mirror those agreements, says Wim Vandenberghe, a competition and regulatory attorney with the Sheppard Mullin law firm in Brussels. "The U.K. would not seek an overhaul of existing food laws as this may lead to significant expense for the U.K. food industry and ultimately an uncompetitive domestic market," he explains.

Also meeting in Slovakia in late September, the Advisory Forum of the European Food Safety Authority (EFSA) issued a "Declaration of Commitment." In it, EU member states agreed to "a range of measures and activities that will ensure that EFSA and Advisory Forum members can together meet future challenges in the area of food safety and so protect European consumers," the agency stated.

Once the U.K. leaves the EU, it will no longer automatically be an EFSA member. The extent to which concerns over Brexit played a role in the declaration is unclear. But the document pledges member states to 18 points, including: strengthening relationships between EFSA and individual state food safety institutions; sharing information on risk assessments; and supporting "the mission and the merging of strategic goals of EFSA and the member states in order to meet the challenges in the area of food and feed safety in all its forms." ■

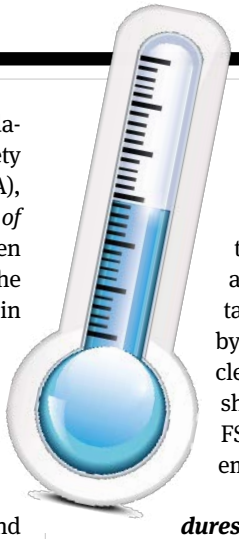
Agres is an award-winning freelance writer based in Laurel, Md. Reach him at tedagres@yahoo.com.

FSMA Update

Top 5 Need-To-Know Aspects of Sanitary Transportation Rule

The FSMA rule emphasizes collaboration in the value chain to help provide safer food while reducing brand risk to shippers, receivers, loaders, and carriers

BY **RANDY FIELDS**



As one of the seven foundational rules of the Food Safety Modernization Act (FSMA), the *Sanitary Transportation of Human and Animal Food* rule has been dubbed the sleeper regulation among the new laws. The rule, whose origins are in the Sanitary Food Transportation Act of 2005, establishes guidelines to prevent practices that would increase contamination risk during the motor or rail transportation of food in the U.S. both intrastate and interstate.

Eliminating risk is always top of mind for a company's lawyers and accountants, but recently finalized FSMA rules, including the *Sanitary Transportation* rule, have caused other company functions to increase their collaboration with their contacts at trading partner companies. Here are the top five things you may not have known about the *Sanitary Transportation* rule in order to comply.

1. Every role has responsibilities. While all seven FSMA rules focus on the grower, manufacturer, retailer, and their facilities, the *Sanitary Transportation* rule also includes third-party transporation companies. The rule defines who among a supply chain's participants are considered shippers, receivers, loaders, and carriers and calls out the responsibilities for each.

2. Keep it cool and keep it clean. In keeping with FSMA's overall intention, the *Sanitary Transportation* rule's responsibilities are preventive in nature. Examples include ensuring temperature control during transportation and storage, and avoiding contamination of products by executing appropriate cleaning steps between shipments. As with all FSMA rules, there are exemptions and exceptions.

3. Operating procedures in writing? Good, keep them for a while. Written agreements between all parties outlining standard operating procedures for transportation of a product are required records for this rule. The rule states records must be maintained 12 months beyond when the procedures are in use. These operating procedures should spell out the requirements for the container, from the design specifications to cleaning procedures to pre-cooling. And don't forget, at each step along the container's trip, documentation must be collected and maintained.

4. You are responsible for stopping the truck or train. An additional provision added to the final rule places a requirement on all parties in the transportation process to stop the sale or distribution of a product if it has been determined that temperature controls have suffered a material failure or other conditions have been detected that render the product unsafe.

5. Document your employee training. Similar to other FSMA rules, there is a training component that requires adequate training of all personnel engaged in transportation operations. They must be

trained to identify and manage potential food safety problems, basic sanitary transportation practices, and carrier responsibilities. A key change here is the training of all personnel must be maintained in writing (or electronically) and be accessible to FSMA inspectors.

The FDA begins enforcing *Sanitary Transportation* in September 2017. Businesses, other than motor carriers who are not also shippers and/or receivers employing fewer than 500 people and motor carriers having less than $27.5 million in annual receipts, have to comply a year later.

The good news is there is a lot that can be done to prepare to comply. After identifying your company's role in transportation, ensure proper procedures are in place, all personnel are properly trained, and all records are being maintained according to FSMA guidelines. Technology is available to address the market need for receiving, storing, sharing, and maintaining regulatory, audit, and insurance documentation all in one location. Since change doesn't happen overnight, the time is now for shippers, retailers, distributors, and carriers to act in order to be prepared. ■

Fields is chairman and CEO of Park City Group, and is CEO of ReposiTrak. Reach him at randy@parkcitygroup.com.

Across The Nation

Amazing Arkansas

Making food safety a priority comes naturally in the Natural State

BY **LINDA L. LEAKE, MS**

Editor's Note: *This is the final installment of a year-long series that highlights the food safety initiatives, programs, and activities implemented in select U.S. states.*

If chicken and rice is one of your favorite go-to comfort dishes, you might want to send a thank you note to Arkansas. The alluring land of the scenic, rugged Ozarks, some 2,000 dazzling underworld limestone caves, and soothing hot springs ranks number two in the nation in broiler production and number one in rice.

Chicken and Rice Dinner

Tyson Foods, Inc. is doing its part to contribute to your favorite chicken and rice recipe, as well as to the strengths of Arkansas food safety and beyond, says Suzanne Finstad, MS, the company's vice president of food safety and regulatory compliance. Based in Springdale, Ark., Tyson is one of the world's largest producers of meat and poultry, reporting fiscal year 2015 sales of $40.6 billion.

More than 4,000 independent farmers have contracts to raise chickens for Tyson Foods, which includes more than 1,700 in the state of Arkansas, Finstad reports. Tyson also operates 15 food processing plants in Arkansas.

"Tyson Foods is an industry leader in terms of food safety and analytics," Finstad boasts. "We take pride in the fact that our programs have been recognized by regulatory authorities as best practices and, in some cases, even referenced as examples in published compliance guidance."

One such example of this, Finstad notes, is Tyson's trademarked Sentinel Site Program for microbiological monitoring of the ready-to-eat (RTE) processing environment.

"The Sentinel Site Program is a rigorous environmental microbiological surveillance program we launched in 1999, well before the regulatory requirements of 9 CFR §430 were promulgated," Finstad relates.

She says that the Sentinel Site Program is designed as an on-going verification of the hazard analysis regarding the potential for post-processing contamination of RTE products with *Listeria monocytogenes* (*Lm*).

"Specifically, it represents an ongoing assessment of the Hazard Analysis and Critical Control Points (HACCP) plan and the conclusion that post-processing contamination of RTE products with *Lm* is not a hazard reasonably likely to occur," Finstad explains. "This conclusion is justified by the data previously collected, which demonstrates that food contact surfaces are not harboring *Lm*. These data continue to be collected and analyzed to assess the ongoing potential for this hazard to occur."

According to Finstad, data are collected through the Sentinel Site Program on a weekly basis from food contact surfaces, non-food contact surfaces, as well as indirect-food contact surfaces in all of Tyson's RTE manufacturing facilities.

"If and when a surface returns a positive test result for *Listeria spp.*, an investigation is conducted and corrective actions are taken before the line is eligible to resume production," Finstad says. "Once production has resumed, the surface is subject to intensified monitoring for *Listeria spp.* to confirm that a harborage does not exist. In the event that any surface on the production line returns a positive test

(Continued on p. 16)

(Continued from p. 15)

result for *Listeria spp.* concurrent with this intensified monitoring, we immediately reassess the HACCP plan and incorporate a critical control point for the control of *Lm*. In the event that test results necessitate finished product testing for *Lm*, a robust sampling plan is employed. This sampling plan is based upon International Commission on Microbiological Specifications for Foods criteria for a severe hazard."

The Arkansas rice industry is also committed to maintaining high food safety and quality standards, according to Kevin McGilton, vice president of government affairs for Riceland Foods, Inc., a farmer-owned cooperative based in Stuttgart, Ark.

Riceland bills itself as the world's largest miller and marketer of rice (and one of the Mid-South's major soybean processors). It provides marketing services for rice (and soybeans) grown by its 6,000 farmer-members in Arkansas and Missouri. Each year, its 1,500 employees receive, store, transport, process, and market more than 125 million bushels (2.5 million metric tons) of grain, McGilton relates.

"Riceland rice mills are held to a high standard of quality and food protection," McGilton emphasizes. "Facilities are registered with the FDA and are subject to the requirements of the Food Safety Modernization Act (FSMA). In addition, they must pass USDA Federal Grain Inspection Service (FGIS) inspections and many mills have FGIS offices inside their facilities. For an even greater degree of quality and food safety, Riceland mills are also certified annually by third-party auditors for compliance to the standards of the Global Food Safety Initiative and the Safe Quality Food Institute."

Arkansas is a very important agricultural state, Finstad emphasizes. "It's home to companies engaged in all aspects of the food chain from harvest, processing/manufacturing, transportation, and retail," she says.

The tremendous presence of the food industry, especially in the Northwest portion of the state, is a great strength of the Arkansas food safety culture, says Steven Ricke, PhD, the Donald "Buddy" Wray Food Safety Endowed Chair and director of the Center for Food Safety (CFS) within the University of Arkansas (UA) System Division of Agriculture, Fayetteville.

Razorback Backing

"The university strives to be supportive of our state's food industry," Dr. Ricke says. "We do all we can to partner with stakeholders, bring new ones into the state, conduct relevant research to benefit the food industry, and act upon related issues as they come up."

Dr. Ricke is especially proud of the Arkansas Security Research and Education Institute, also known as ASCENT, a collaboration with the UA College of Engineering for which he serves as a co-director. One of ASCENT's key research initiatives is food and water security, he notes.

> "Arkansas stands out because of the support by, and focus on, the food industry resulting from the large scale of food production in the state," Dr. Cook explains.

"ASCENT addresses food biosecurity and cybersecurity, and it is innovative in that it links food safety to big data," Dr. Ricke relates. "As more data is generated from whole genome sequencing of foodborne pathogens from food and other sources, the ability to not only process that data for in-depth analyses but protect such data from external cyber threats becomes critical. Part of ASCENT's goal is to work with industry to tackle these issues and also provide the training tools for the next generation of UA graduates that work in the food industry."

"For the first time, we are leveraging tools from the engineering and computer science space to address food security challenges," adds Chase Rainwater, PhD, a UA associate professor of industrial engineering and co-director of ASCENT. "The amount of data available to analysts in the food domain is both intimidating and exciting. It is pivotal that the food industry brings in the best tools to learn from this information. Students from engineering have already benefited from partnering with Dr. Ricke's lab and the solutions we are developing in the machine learning space will be of interest to a number of players in the industry."

The CFS is a key strength of food safety programs and initiatives in Arkansas, concurs Harrison Pittman, JD, LLM, director of the National Agricultural Law Center (NALC), also based at UA's main campus in Fayetteville.

"In conducting research on both safety and quality of foods, the CFS not only serves stakeholders and consumers but also provides a platform for interdisciplinary research and outreach with faculty and others in the UA system and beyond," Pittman says. "Arkansas also stands out nationally in this area because of the Arkansas Food Innovation Center (AFIC). AFIC works with food entrepreneurs in developing value-added products, which specifically includes ongoing workshops and programs that address food safety."

According to Pittman, the NALC, which is touted as "the nation's leading source for agricultural and food law research and information," works closely with colleagues in the CFS and AFIC. "The NALC provides objective educational outreach on issues such as states' cottage food law, FSMA, and related legal liability concerns," he explains.

Collaboration is the primary strength of food safety programs for Arkansas, says John Marcy, PhD, CFS, UA professor and poultry processing extension specialist. For starters, he relates, UA is a strong partner of the Arkansas Agriculture Department, noting that, along with poultry and rice, Arkansas is also a major producer of fruit and vegetables.

"Having Walmart, the world's largest retailer and purveyor of food here, also means there is a spotlight on the safety of things grown in Arkansas," Dr. Marcy points out.

The Arkansas Department of Health, Arkansas Department of Parks and Tourism, the Arkansas Hospitality Association, along with the UA System Division of Agriculture Cooperative Extension Service (CES) provide up-to-date information and education to food service managers in the private sector and to all of the state parks within the Arkansas system on an annual basis, Dr. Marcy says.

"The CES is working in cooperation with the Arkansas Economic Development Commission—Manufacturing Solutions to

make the new FSMA Food Safety Preventive Controls for Human Foods training available throughout the state in a timely manner," Dr. Marcy relates.

The CES hosts a quarterly informal educational exchange on HACCP and food safety between the poultry and meat processors from a four state area and the Springdale District Office of the USDA Food Safety Inspection Service Office of Field Operations, Dr. Marcy adds.

Food safety programs and initiatives in Arkansas are exceptional, says Peggy Cook, PhD, CFS, with Cargill Turkey and Cooked Meats Food Safety and Regulatory, Springdale.

"Arkansas stands out because of the support by, and focus on, the food industry resulting from the large scale of food production in the state," Dr. Cook explains.

For its part, Cargill is a global company and contributes to food safety initiatives in Arkansas, she relates. "Ensuring the production and distribution of high quality, wholesome, affordable, and compliant products is core to Cargill's commitment to the communities and customers we serve," Dr. Cook emphasizes.

Dr. Cook is the 2016 president of the Arkansas Association for Food Protection (AAFP), a strong and active affiliate chapter of the International Association for Food Protection. The 250-member AAFP holds an annual two-day conference each September, complete with a tradeshow and a host of prominent U.S. food industry speakers.

"In 2016 we were very honored to offer the first ever FBI Food Defense Workshop in the U.S., during which attendees could gain a certificate of participation from the FBI," Dr. Cook relates. "We worked with the FBI and the U.S. Department of Justice to present a tabletop exercise that focused on food defense at poultry processing facilities."

Insider Insights

"Arkansas has always been a big player in food and prepared meals because of a central location, clean water, being number one in rice, a big producer of soybeans, and having a history of growing produce like spinach, apples, watermelon, and tomatoes," says Brian Umberson, a lifelong Arkansas resident who works as a sales representative for Sample6, a purveyor of pathogen control solutions and technology.

"The real advancement of the Arkansas food processing sector came when Tyson exploded from 1940 to today which modeled the way for more food processors and helped establish infrastructure for water and other utilities," Umberson believes. "Walmart and Tyson created a grocer, food processor, distribution, and total supply chain that became the Arkansas food sector we know today. So it can be said we take farm to fork to a different level here in Arkansas." ■

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For bonus content, go to December/January 2017 issue on FoodQualityandSafety.com and click on "Food Safety Comes Naturally to Arkansas."

Evolution of Food Laws

The Earliest Food Safety Regulations

Important moments in history that have helped shape today's U.S. food system

BY **LIBBY THOMA**

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Editor's Note: *This first article in a three-part series will review history of food laws and their impact on industry progress.*

Laws governing the manufacture of foods and beverages have been in existence for thousands of years. In ancient civilizations, these laws were created to ensure fair trade practices through proper labeling and accurate declaration of weights and measures to prevent adulteration and for taxation purposes. Regulations for beer manufacturing can be traced back to the Code of Hammurabi, written in 1700 B.C. during the Babylonian era, and laws written to control the sale of wine and bread go back to the Roman Empire. During medieval times, the Assize of Bread and Ale was enacted to establish proper weights, quality standards, and prices of bread and beer sold in England. For example, each loaf of bread was required to be labeled with the baker's indentification "mark" to regulate quality and ensure fair taxation. In 1215, the Magna Carta established standard measures for quantities of wine, corn, potatoes, and other goods to be sold or made available for sale in the English villages.

The American colonists also implemented food regulations soon after settling. In 1646, the General Court of Massachusetts Bay Colony enacted the Assize of Bread that was nearly an exact replica of the regulation established 400 years prior in Britain. The Massachusetts "Act Against Selling Unwholesome Provisions," passed on March 8, 1785, is widely believed to be the first food safety law enacted by the fledgling U.S. government.

The beginnings of the U.S. regulatory agencies governing today's food industries can be traced back to 1837 when Henry Leavitt Ellsworth was appointed the Commissioner of Patents, a position within the Department of State. Ellsworth sought to improve the country's agricultural industry by widely distributing improved varieties of seeds. With the establishment of the Agricultural Department as a division of the U.S. Patent Office in 1839, Ellsworth became known as the "Father of the Department of Agriculture." About 20 years later, President Lincoln established the independent USDA and appointed Isaac Newton as the agency's first commissioner. In its early years, the agency was referred to as the "People's Department" since it did not yet have Cabinet representation—this was not achieved until Feb. 9, 1889 when President Cleveland signed a bill finally elevating the USDA to Cabinet level.

The FDA, America's oldest consumer protection agency, traces its origins to the USDA's Division of Chemistry. In 1883, the agency appointed Harvey Wiley to chief chemist. He investigated adulteration of pharmaceuticals and foods, and with muckraking political activists, he worked to raise awareness of hazards in these industries. Significant progress was made in 1905 when Upton Sinclair published "The Jungle," a brutally honest novel that brought national attention to the horrific conditions in the Chicago meat packing industry. Sinclair's primary intention was to bring awareness of the poor working conditions of the immigrant workers. He stated change resulted "not because the public cared anything about the workers, but simply because the public did not want to eat tubercular beef." Regardless, as a result of the public's outcry, both the Federal Meat Inspection Act and the Pure Food and Drugs Act, also known as the Wiley Act, were signed on June 30, 1906 by President Roosevelt. These bills gave authority to the agencies in instituting mandatory inspection of meat-processing plants and to prohibit misbranded and adulterated food in interstate commerce. Two decades later, the Department of Chemistry was reorganized into a separate regulatory branch

known as the Food, Drug, and Pesticide division. In 1930, the name was shortened to the Food and Drug Administration (FDA).

In 1938, the FDA was given more definitive jurisdiction when President Roosevelt signed the Federal Food, Drug, and Cosmetics Act. Replacing the Pure Food and Drugs Act, this body of law was initiated after the death of more than 100 patients from sulfanilamide medication that was adulterated with diethylene glycol. Since then, the bill has been amended several times and has broadened the agency's jurisdiction to include oversight of medical devices, bottled water, and many other related industries.

Laws for Manufacturing Processes

The FDA proposed the regulations embodying the current Good Manufacturing Practices (cGMPs) in 1968 after several more decades of continued tragedies due to food safety incidents. The regulations were finalized in April of 1969 and were published as Part 128 of the Code of Federal Regulations. This was re-published as Part 110 of the CFR in 1977. The original cGMPs were written very generally and did not specify exactly what was required of facilities to comply with the regulations. The vagueness of the laws made them difficult for the agency to enforce, so the FDA improved the wording of the laws and published the revised version, 21 CFR 110, in 1986. Industry-specific GMPs were also included in 21 CFR Parts 100 through 169 for infant formula, thermally processed low-acid canned foods, acidified foods, and bottled drinking water.

During the late 1950s, NASA and Pillsbury food engineers and scientists created a revolutionary approach to food safety that built quality into the product with the intent of ensuring the utmost safety of the food for the manned space program. This concept evolved into what is now known as HACCP: Hazard Analysis and Critical Control Points. In 1971, the concept was presented by Pillsbury at the National Conference on Food Protection. Three years later, FDA incorporated the concepts of HACCP into its low-acid and acidified food regulations as a response to outbreaks of *Clostridium botulinum* poisonings in commercially-canned food. Since the FDA implemented HACCP, these outbreaks have virtually been eliminated. But public outcry for safer meat products was voiced again in 1993 after an outbreak of *E. coli* O157:H7 in undercooked meat patties, resulting in four deaths and over 400 illnesses. The USDA-FSIS began to investigate the benefits of HACCP's scientific approach to food safety versus the method of sensory inspection that was then employed by onsite USDA inspectors. As a result, the USDA enacted the Pathogen Reduction/HACCP Systems ruling on July 25, 1996. The laws focus on preventing and reducing microbiological pathogens in raw products that can cause illness. They also clarify the roles and responsibilities of industry and government for producing and ensuring safe foods. The widespread implementation of HACCP caused the CDC to formally recognized HACCP's approach to food safety as an important factor in overall decline of bacterial foodborne illnesses.

Food Safety Today

In the 1990s, consumer confidence in the food industry was low after high-profile debacles such as Great Britain's BSE outbreak, the U.S.'s *E. coli* 0157:H7 outbreak, and Belgian's Dioxin Affair. CEOs from major food retailers around the world addressed the concerns by establishing the business-driven Global Food Safety Initiative (GFSI) in May 2000. The group's food safety experts collaborated to create a standardized set of requirements designed to ensure safe food supplies worldwide. These requirements are contained in the GFSI's Guidance Document that was published in August of 2001. GFSI stakeholders formally accepted select food safety management schemes that met the Guidance Document's requirements in June of 2007. Today, food manufacturing facilities strive to achieve GFSI certification through independent third-party audits conducted against requirements in the scheme of their choice. Although GFSI does not have regulatory authority over the food manufacturing industry, it does have tremendous financial influence, and facilities reap the economic benefits of certification to these globally recognized standards.

The FDA's Food Safety Modernization Act is the most modern body of legislation governing the U.S. food industry. Signed into law by President Obama on Jan. 4, 2011, it's FDA's first major regulatory overhaul in 70 years. The law requires facilities to develop documented food safety plans that identify all potential hazards associated with the process/product, implement risk-based preventive control measures that minimize or prevent identified hazards, and describe methods of prevention. It also updates the cGMPs and mandates specific preventive control programs, both of which will be discussed in the next article of this series. ■

Thoma, a food safety and quality professional with nearly 20 years of experience in food manufacturing and food safety auditing, has worked for NSF International for four years as both a GFSI certified auditor and as a technical specialist in the Supply Chain Food Safety group. Reach her at lthoma@nsf.org.

Reducing Allergen Recalls Under FSMA

Part 117 of FSMA can help organizations minimize risk to allergic consumers and avoid costly recalls

BY **CORNELIUS HUGO**

With the Food Safety Modernization Act's preventive controls rule now in effect, it's the perfect time to explore one of the most widespread issues in the food industry—allergen recalls. Let's explore the issues at hand, the challenges, and the solutions.

The Issues

Food allergens are a scary reality for many consumers. Roughly 3-6 percent of children and 2-4 percent of adults are allergic to one or more of the eight common foods that cause 90 percent of all food allergen reactions in the U.S. Known as "The Big 8," these food groups include milk, egg, peanut, tree nuts (14 of them including coconut), fish (species specific), crustacean shellfish (species specific), wheat, and soy. The Big 8 are used in tens of thousands of food products that use one or more of these allergens as an ingredient in their formulation.

An allergic reaction can be triggered by a minuscule amount of any one of these allergens and the reactions vary, ranging from a tingling of the mouth and lips to vomiting and diarrhea, to respiratory difficulties, blood pressure issues, and even death due to anaphylactic shock. Every year, about 3,000 consumers die and tens of thousands seek emergency medical treatment to reverse the effects of their allergic reactions.

The only way allergic consumers can protect themselves is by completely avoiding the allergen they are allergic to. In order to succeed, this involves three fundamental principles:

1. Allergic consumers are responsible for reading the ingredient statement of the food to determine whether or not the particular item contains the allergen they must avoid;

2. Allergic consumers must always be prepared for accidental exposure by carrying an epinephrine injector and emergency contact information; and

3. Those manufacturing, preparing, and serving food must provide safe food by preventing cross-contact, as well as accurate information to enable consumers to avoid allergen exposure.

The Challenges

In spite of the obvious associated health hazards and the seemingly simple solutions to allow consumers to avoid specific allergens, the food industry is still struggling to bring this issue under control. The pie chart, on page 23, containing the annual Reportable Food Registry for fiscal year 2015 shows that allergen recalls continue to be the number one reason for food recalls in the U.S., with 47 percent of total recalls. This is followed by two pathogens, which combined, account for another 44 percent of the recalls.

Perhaps more importantly would be to know *why* allergens are the number one reason for food product recalls in the U.S.

A search for root causes leads us to two basic operational failures, one dealing with label control and the other to allergen cross-contact. First, and most common, is the failure to declare the allergen(s) contained in the product on the information panel of the package, as required by labeling regulations. Examples include outright omission of the allergen or not using the common name. Such labeling errors are the result of lack of controls at the supplier of labels or computer errors in the in-house printing of finished product labels. Another example is putting a product containing an allergen in the wrong packaging material, say of another similar product, which does not contain the allergen. The omission of declaring an allergen at the supplier level can result in a carry-through of such "hidden" allergen into the final product, again resulting in a misbranded finished product in the market. Another example of labeling failure is the result of a product formula change that is not carried through to the label.

The second type of failure that leads to a misbranded product subject to recall is the result of allergen cross-contact. Basic root causes include ineffective allergen cleanups of food contact surfaces of shared equipment and utensils; inappropriate cleaning practices, such as the use of high air or water pressure; not using dedicated utensils for allergens; inappropriate personnel practices and clothing; lack control of rework (like-into-like); and the accidental use of a wrong ingredient containing an allergen. Unfortunately, these types of operational failures are invisible to the consumer who will buy the product based on reading the content of the ingredient declaration.

In short, the problem of allergen recalls can be reduced to two basic issues. First, failures that lead to inaccurate labels and second, failures that lead to unintended allergens being in the final product. Both issues can be very detrimental to allergic consumers, and invariably lead to costly recalls.

The Solutions

Some solutions include more effective label or package control at packing/labeling process steps. For others problems, such as omitting allergens from labels, thorough root cause analysis is needed. The unintended presence of an allergen in products due to cross-contact or other processing/operational failures will also need root cause analysis to identify the basic issues that lead to these failures.

I'll start by looking into ways and means to prevent allergen cross-contact during manufacturing operations. The Preventive Controls Rule, namely Part 117, revised several provisions of the current Good Manufacturing Practices (cGMP), Part 110 to address and control potential allergen cross-contact as part of the preventive controls. These new requirements are contained in the new Part 117, Subpart B—cGMP.

On more than 20 occasions, the phrase "to protect against cross-contact" was added to the different components of the new cGMP, aiming to reduce failures that result in unintended allergens being added to a product. These additional preventive controls were added to:

- Personnel hygienic practices;
- Outer garments;
- Design and construction of plant equipment and utensils (including location, materials, construction and finishing, seams of food contact surfaces, separation/partition of operations, ventilation systems, dust control, enclosed systems, and timing of manufacturing and non-manufacturing activities);
- Sanitation of equipment and utensils with special emphasis on food-contact surfaces;
- Sanitation of nonfood-contact surfaces;
- Control of single-service articles such as utensils, paper cups, and paper towels;
- Storage and handling of cleaned portable equipment and utensils with food-contact surfaces; and
- Processes and controls (such as manufacturing procedures, testing and segregation of raw materials and ingredients, reuse of water for washing, rinsing and conveying of food, inspection of containers, handling and storing of raw materials and ingredients, identification and segregation of ingredients that are food allergens, work-in-process and rework, transfer of food allergens to other foods during manufacturing, and protection of finished product against cross-contact during warehousing and distribution).

(Continued on p. 23)

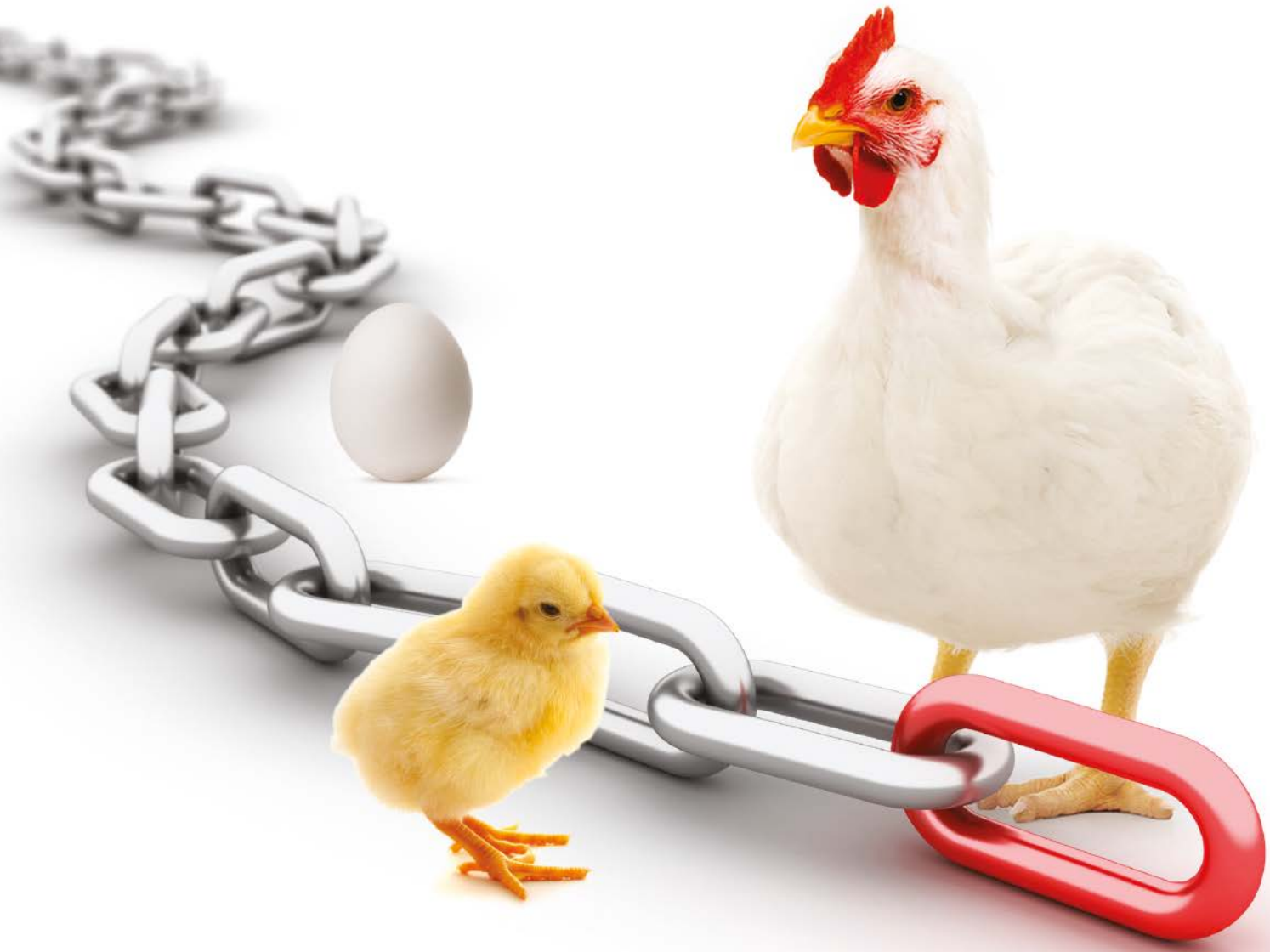
Consolidated Standards for Inspection Table

Operational Methods Category
1.1 Rejection of shipments/receipt of dry goods
1.2 Storage practices
1.7 Carry-over and rework
1.8 Dust collection and filtering devices
1.9 Bulk material handling
1.11 Processing aids
1.12 Material transfer
1.16 Waste material disposal
1.17 Ingredient containers, utensils, and tools
1.18 Allergen handling
1.20 Single-service containers
1.23 Cross-contamination
1.25 Finished product transportation

Maintenance for Food Safety Category
2.3 Layout
2.4-2.7 Floors, drains, walls, ceilings, and overhead structures
2.9 Air makeup units
2.13 Cross-contamination prevention
2.14 Equipment and utensil construction
2.18 Transportation equipment
2.19 Parts storage

Cleaning Practices Category
3.3 Cleaning tools and utensils
3.4 Cleaning equipment
3.5 Daily cleaning
3.6 Operational cleaning
3.7 Periodic cleaning tasks/ product zone cleaning
3.8 Maintenance cleaning
3.9 Non-product zone and support area cleaning
3.10 Clean-in-place systems
3.11 Clean-out-of-place system

Adequacy Category
5.9 Allergen control program
5.13 Receiving program
5.18 Non-conforming product program
5.19 Approved supplier program
5.20 Specification program
5.21 Letters of guarantee or certifications
5.23 Food Safety Plan
5.24 Specialized testing
5.25 Release procedures
5.26 Design standards



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(Continued from p. 21)

A great way to approach these newly regulated allergen cross-contact preventive controls and update your current Allergen Control Program is:

- Obtain a copy the FDA's summary revisions to the cGMP and additional requirements to address allergen cross-contact;
- Have your food safety team review and understand the scope and intent of these new allergen cross-contact preventive measures;
- Carefully walk the plant with these regulations in mind to verify conformance;
- Identify non-conformance issues, address them, and update your Allergen Control Program, including new documentation and records, as necessary;
- Identify new education/training needs and make them part of your allergen control training;
- Carry out such training and document it; and
- Implement verification activities to ensure compliance with new allergen cross-contact preventive controls.

As the team walks the plant, it is critical that shared equipment and production schedules designed to minimize allergen cleanup after unique allergens have been used be kept in mind to identify specific allergen cleanup as potential preventive controls in the Food Safety Plan. In other words, by asking "What is the likelihood of the hazard (allergen cross-contact) in the absence of the preventive control (cleanup after the unique allergen)?," the team will be able to identify specific allergen cleanups that are essential for food safety, and those should be treated as Preventive Controls under Part 117.

While some operational changes and adjustments may be easier to implement, in some cases changes to the design, maintenance, and operations of equipment may be necessary. These may take more time and capital to develop and implement.

Let's now take a look at the failures resulting in misbranded food products. The most troublesome mistakes (not declaring the allergens, using the wrong package or label, and wrong terminology) account for over half of failures and can be minimized, if not eliminated, with some straightforward labeling-related preventive controls.

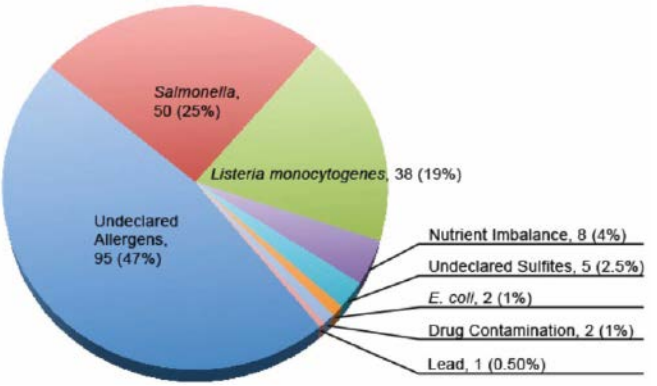
By comparing the samples representing each shipment of labels with their proofed versions, this simple verification procedure should lead to a correction at receiving if any labels arrive with printing errors. In such a case, the shipment would be returned to the supplier or destroyed. This assumes that other potential causes such as splices and mixed lots have been addressed as well. This preventive control at receiving should minimize, if not prevent, entry of non-compliant labels into the facility.

Being reassured that only correct labels are stored in the warehouse is no guarantee that these will end up with the right product. Consider implementing another potential preventive control at packaging/labeling of the finished product. This effort constitutes a verification procedure to assure a proper match between the label/package/container and the product that will be added. There are many ways of achieving this goal that are dependent on the technology used, the complexity of the manufacturing process, the quantity of products, the number of allergens, and other factors. Similar procedures can be applied to avoid failures with in-house label printing processes.

Using these two potential labeling Preventive Controls, one at receiving and another at the process step where the label and the product come together, will go a long way in minimizing the risk to allergic consumers and the costs of recalls.

The possibility of designating these two measures as Preventive Controls under Part 117 is quite reasonable, depending on the complexity of the manufacturing process. Again, the key question would be to ask, "What is the likelihood of the hazard, namely a misbranded product, in the absence of the Preventive Control?" In the first case, a misprinted label would be received and accepted. Such mistake could still be caught and prevented from going further in the packaging/labeling step. Still, catching the mistake at receiving is far less costly than catching it when a product has already been packaged in mislabeled containers. In the second case, that is in the absence of a labeling verification activity at packaging/labeling, the likelihood of a misbranded product reaching the consumer increases dramatically. So identifying the measure as a Preventive Control at this process step would be a prudent decision under Part 117.

Reasons for U.S. Food Recalls, FY15



SOURCE: FDA 5TH ANNUAL REPORTABLE FOODS REGISTRY (MAY 2016)

A resource for companies wanting or needing to challenge their allergen control program is AIB's Consolidated Standards for Inspection. It contains many requirements that are directly or indirectly associated with allergen control, as seen in the Standards table on page 21.

Future success in preventing misbranded food products due to cross-contact or inaccurate labels will go a long way in reducing the number one reason for food recalls in the U.S. This can be achieved by elevating a couple of current practices to the level of a Preventive Control under Part 117, and managing them similar to a Critical Control Point, with monitoring, correction/corrective action, verification, validation (for allergen cleanup procedures), and documentation. Employee education and training to become Qualified Individuals related to allergen control and the production of safe, legal food will be of uppermost importance for these modifications to your Food Safety Plan to succeed. ■

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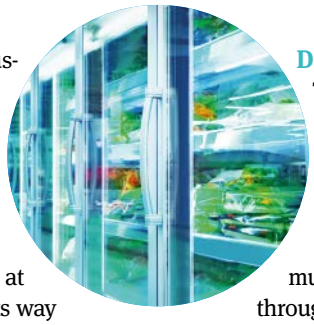
Handling Recalls with Transparency

Whole-chain traceability can proactively manage a food safety crisis

BY **KATY JONES**



Recalls are an inevitable part of the food industry. Every brand will experience a recall, whether voluntary or mandated, at some point or another. The secret sauce to surviving a quality or contamination issue, keeping consumers safe, and preserving brand reputation fundamentally boils down to transparency.

With the health and wellbeing of consumers at stake if an undeclared allergen or impurity finds its way into a brand's supply chain, the best possible course of action is to scrutinize and keep impeccable records of the chain, and each product moving through it.

It is well-known that the food supply chain is increasingly more complex, as food passes through several stages from farm or factory to someone's plate. Fortunately, the focus of the broader food industry and the government, as well as innovations in technology, are making it easier than ever to comprehensively track the chain.

Going Beyond "OUOB"

The food industry is swiftly moving beyond the linear "one-up and one-back" (OUOB) approach to comprehensive supply chain transparency. Awareness of where a product directly came from and where it is going next is no longer an acceptable standard of transparency if a company wishes to best prepare for and manage recalls. Underscored by federal regulations like the Food Safety Modernization Act (FSMA) and the Foreign Supplier Verification Program, the broader industry is shifting towards a preventative approach to safety matters, rather than a reactive method.

Considering the variety of technology advancements now available to enable full supply chain transparency, brands looking to bounce back from a recall and mitigate future issues have the solutions readily available. Through implementing whole-chain traceability software, brands are able to visualize the supply chain from top to bottom, and trace each product down to the specific farm, package date, and lot it originated from. Tracing that information through each step in the supply chain allows brands to know whether a specific batch of tainted spinach ended up on a sandwich, in a can of soup, or in a farmer's market—allowing the brand to proactively manage the tainted products without disrupting their entire chain or wasting undamaged produce.

The OUOB traceability approach is especially dangerous when handling high-risk, perishable foods, like produce or meat—which are often the culprit of recalls. According to a recent study in the Journal of Business Logistics titled, "Tracing Bad Products in Supply Chains" by Dr. Kaitlin Wowak, assistant professor of management at Notre Dame, "perishable products, like fresh produce and meats, flow through the supply chain very quickly. And while federal regulations mandate that firms have traceability one step up and down the chain, this may not be sufficient for these perishable products. In those situations, there is often a gap in the information received about the product, say a positive *Listeria* test, and where that product went in the supply chain."

Data is of the Essence

The time it takes the recall team to identify the root cause of an issue, notify the appropriate audiences, and remove it from the supply chain could be the difference between sick consumers and serious brand implications.

When faced with a safety or quality issue, communicating information to relevant parties is necessary throughout the process. Particularly as FSMA takes effect, if a brand faces a safety issue and must recall product, it must first notify regulatory establishments and submit detailed documentation and data for an investigation to proceed before the recall can commence. This can be delayed if a brand does not have organized records of their supply chain data and must spend hours sorting through file cabinets, Excel sheets, or emails for appropriate documentation, or liaising with various suppliers for the information. The longer it takes a company to comply with federal regulations and submit the proper data around a recall, the more likely consumers, and the brand, are at risk.

Having a robust supplier management system backed by an end-to-end traceability platform help a brand manage recall situations immediately, as all of the necessary information will be at their fingertips, securely housed within one platform. This allows companies to quickly gather and allocate necessary data like food safety documentation, audits, and assessments to the appropriate officials—complying with all of the latest recordkeeping requirements.

The Transparent Approach

As a result of FSMA, the FDA will no longer put up with poor handling of contamination or quality issues. Brands are no longer able to blame a supplier's lack of transparency or unreliable records for exposing consumers to unsafe products—the brand is held more accountable than ever.

As the brand image is now perpetually on the line, recovering from a poorly handled recall is more difficult than ever before. In the coming months, the industry will experience added scrutiny from FDA auditors, increased mandatory recalls, even the closing of facilities due to noncompliance around safety. While full transparency and proactivity were optional in the past, they are now fundamental components of a brand's safety plan if they are to adapt to the changing industry landscape.

While recalls are an inevitable part of the food industry, what sets a company apart is how they prepare to handle these issues. Through implementing supplier management and whole-chain traceability software, brands can keep their supply chain fully transparent and compliant with the growing set of federal regulations. With consumer wellness and brand reputation on the line, proactivity and transparency can ensure that a company is one step ahead of an outbreak at all times. ■

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Special Report

As Oceans Warm, *Vibrio* Increases

The bacteria are moving north, causing new concerns over the safety of oysters

BY **LORI VALIGRA**

For centuries, oyster lovers have slurped down raw shellfish, enjoying the taste plus the fact they are low in calories and high in protein, iron, and other nutrients. But as ocean temperatures have warmed, some of the shellfish have become incubators for various species of genus *Vibrio* bacteria, some of it harmless, some of it causing serious illness or even death in those with compromised immune systems.

According to the Molluscan Shellfish Institute of North America, Americans eat about 2.5 billion oysters each year, farmed rather than native-grown, as the latter populations have declined due to disease and other factors over the years.

Though *Vibrio* occur naturally in ocean saltwater and around estuaries and brackish water, their escalation in oysters, which filter feed and thus build up the bacteria, didn't start until the 1970s when growers who had avoided selling the shellfish during the summer months to give them a chance to reproduce instead began selling them year-round, says Robert Tauxe, MD, MPH, deputy director, CDC's Division of Foodborne, Waterborne, and Environmental Diseases based in Atlanta.

"The oyster harvests in the old days were suspended in the summer to let the oysters breed," says Dr. Tauxe. "That changed in the 1970s and that is when *Vibrio* surfaced."

He also notes while *Vibrio* occurs naturally, there is some suspicion that its movement from the Gulf of Mexico to northern U.S. oceans may be the result of its transfer in ballast water on ships, especially those in oil ports.

"Warm water increases the prevalence of *Vibrio* infections," Dr. Tauxe says. Though infections are rare, they are most prevalent within the Gulf of Mexico coast from April to October. "It's particularly important for people in the Gulf area during warm seasons to stay out of the water. *Vibrio* are champions among multipliers. They can multiply every 15-18 minutes."

Up to 45,000 *Vibrio* cases occur a year, with most causing watery diarrhea, vomiting, abdominal pain, and even death. Of the 1,252 cases of vibriosis recorded in 2014, there were 326 hospitalizations and 27 deaths, according to the CDC's Cholera and Other *Vibrio* Illness Surveillance system.

CDC surveillance epidemiologist Erin Burdette, MPH, adds that *V. parahaemolyticus*, the most common species of *Vibrio*, has been reported as far north as Maine in recent years. In 2004, an outbreak occurred in Alaska that was linked to oysters raised locally during one of the state's warmest summers. In other cases, oysters are imported from other areas of the country and eaten elsewhere: therefore, harvest origins need to be traced if there's a disease outbreak. During the winter, *Vibrio* cannot multiply but instead become dormant and drop to very low levels until the water warms again.

A Sentinel for a Changing World?

Dr. Tauxe likened *Vibrio* to a sentinel in the foodborne illness world. "There are other organisms that are impacted by an increase in heat to the water," he says. "We expect to see new problems emerge as the landscape of foodborne infections changes." This includes movement of pathogens like *Vibrio* into warming northern oceans and global food sourcing.

The three most frequently seen *Vibrio* are: 1) *V. parahaemolyticus*, which is the most common and is creeping up both U.S. coasts and their northern borders, 2) *V. alginolyticus*, which is the second-most common and whose infectiousness is associated with direct contact with sea

CDC

"We expect to see new problems emerge as the landscape of foodborne infections changes."

—**Robert Tauxe,** MD, MPH, deputy director, CDC's Division of Foodborne, Waterborne, and Environmental Diseases

water, and 3) *V. vulnificus*, which has the highest death rate, related to the consumption of raw shellfish and exposure to open wounds.

V. parahaemolyticus falls in the same family of bacteria that causes cholera. The bacteria do not change the taste, smell, or look of an oyster, so it's hard for consumers to tell if the oyster has the bacteria or whether the strain it has is indeed infectious.

Species such as the potent *V. vulnificus* can enter the body through a wound. Those who have liver disease, chronic illnesses like diabetes, or are otherwise immune-compromised are particularly susceptible and should either stay out of the water or cover their wound with a waterproof bandage, according to Dr. Tauxe. That being said, *V. vulnificus* infections are uncommon—with just a couple 100 cases a year, half from wounds and half from raw oyster consumption.

Over the past 20 years, *E. coli* 0157, *Yersinia*, *Campylobacter*, and *Listeria* culture-confirmed infection rates have decreased significantly while *Salmonella* showed no change. Comparatively, *Vibrio* cases showed a sharp rise (see Chart 1), according to the CDC's Foodborne Diseases Active Surveillance Network (FoodNet). In 2015, *Vibrio* cases were up 34 percent compared to 2006-2008. Relatively, *E. coli* 0157 was down 30 percent over the period.

Within the *Vibrio* types, *V. Vulnificus* has been decreasing in recent years, likely the result of increased control of post-harvest time and temperature requirements of the shellfish industry, Jason Strachman-Miller, an FDA spokesman, said in an email.

"A decrease of over 30 percent has been observed for 2013 and 2014," he wrote. "While the illness records for 2015 have not been finalized, it is expected that this decrease will continue."

However, annual illnesses for *V. parahaemolyticus* in 2013 and 2014 almost doubled, Strachman-Miller noted, likely because of the emergence of the Pacific Northwest type of *V. parahaemolyticus* in the Mid and North Atlantic. He stated preliminary numbers for 2015 indicate a return to the baseline, although illness data is not finalized.

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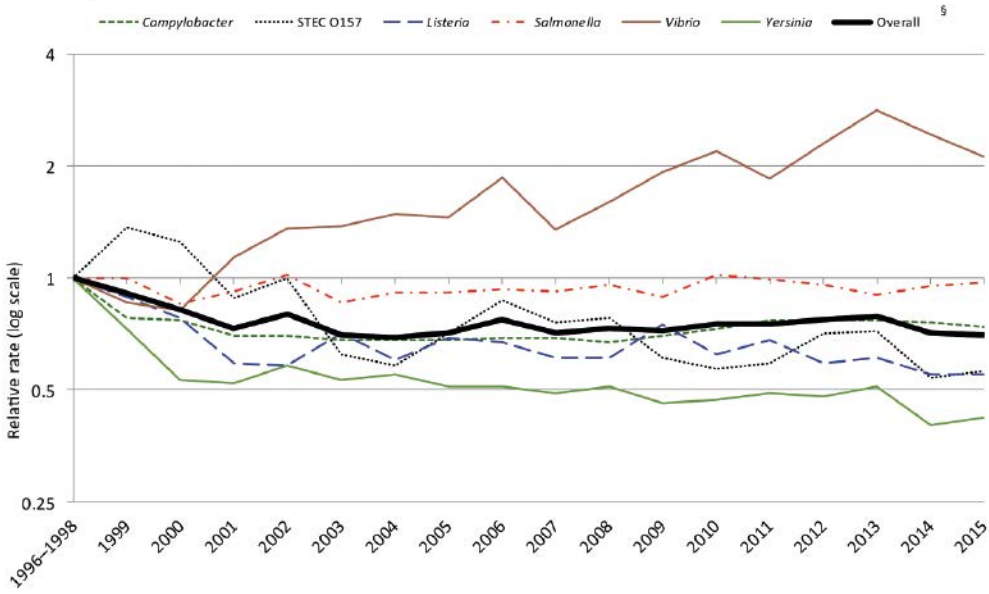
Chart 1. Relative rates of culture-confirmed infections with *Campylobacter*, STEC* O157, *Listeria*, *Salmonella*, *Vibrio*, and *Yersinia*, and overall measure of change, compared with 1996–1998 rates, by year, FoodNet 1996–2015†



Dr. Tauxe says the CDC supervises the human health aspects of *Vibrio* while the FDA supervises shellfish sanitation programs. State health departments send out alerts in an attempt to ensure consumer safety.

Reducing Risk of Vibriosis

If you are in a group more likely to get Vibriosis, wear clothes and shoes that can protect from cuts and scrapes when in brackish or salt water, place waterproof bandages over any cuts, and wear protective gloves when handling raw seafood.

Before cooking, discard shellfish with open shells. For shellfish in the shell, either:

- Boil until the shells open and continue boiling 5 min. more, or
- Steam until the shells open and continue steaming for 9 min. more.

Discard shellfish that do not open fully after cooking.

For shucked oysters, either:

- Boil for at least 3 min.,
- Fry in oil for at least 3 min. at 375° F,
- Broil 3 in. from heat for 3 min., or
- Bake at 450° F for 10 min.

Always wash hands with soap and water after handing raw shellfish, and avoid contaminating cooked shellfish with raw shellfish and its juices.

SOURCE: CDC

Testing the Waters

Currently, says Dr. Tauxe, the needed markers and tests for *Vibrios* are not in place.

Cheryl Whistler, PhD, researcher and associate professor of microbiology and genetics, University of New Hampshire, Durham, N.H., and her colleagues are working to change that. They are using whole genome analysis to assess genetic characteristics of distinct *Vibrio* populations in the Atlantic. The hope is that the information will help with more accurate trace-back. So far, their analyses are allowing identification of strain-specific genetic loci they can use to develop strain-specific quantitative polymerase chain reaction, or PCR, detection assays for rapid quantification of the strains causing the most concern.

"We can quantify the total degree of all strains [in the water]," Dr. Whistler says. "While we can detect the total number of *Vibrio*, we want to be able to quantify which of them are pathogens." Not all *Vibrio* are pathenogenic. "It's like looking at football spectators and trying to find only those with red hair, blue eyes, and no freckles."

Dr. Whistler says she is interested in whether validating specific strains will be a better predictive tool in modeling the combination of conditions that increase risk and warns of cross-contamination. "The first case of *Vibrio* was a case of cooked oysters put back on the ice the raw product was on," she says.

So while her tests can tell there is *Vibrio* in the water and its prevalence, ultimately it's up to consumers to choose what they eat and how they eat it.

"Anybody who wants to eat an oyster should have the choice to cook it or not," she says. "Raw oysters are a delicacy. Cooking loses the flavor and texture."

Making Oysters Safe

There are some methods that have helped diminish harm from *V. parahaemolyticus*. For example, harvesters need to refrigerate oysters as soon as possible after catch to decrease the temperature, Dr. Tauxe explains. He says that approach has worked well in Japan, which had a big problem with the bacterium. The cooling doesn't kill the oysters, which would alter their taste and texture, but prevents future growth of the bacterium.

Cooking also kills *Vibrio*, but the cooking or steaming must continue even after the shells open—five more minutes for boiling and nine more for steaming (see above sidebar). Hard freezing will also reduce the bacterium count, but it kills the oyster and changes its taste and texture. Commercial pressure chambers are used as well.

In 2003, after an outbreak of *V. Vulnificus* killed five people, California instated a new requirement that oysters sourced from the Gulf of Mexico from April to October be cooked or treated, in some cases using high pressure and heat pasteurization, Dr. Tauxe states, adding that there now are no deaths.

"It [the program] was a pretty clear success," he says. "The California strategy is worth thinking about. If it's the warm months and the oysters are from warm water, people should be aware of the risk [of eating raw oysters]." ■

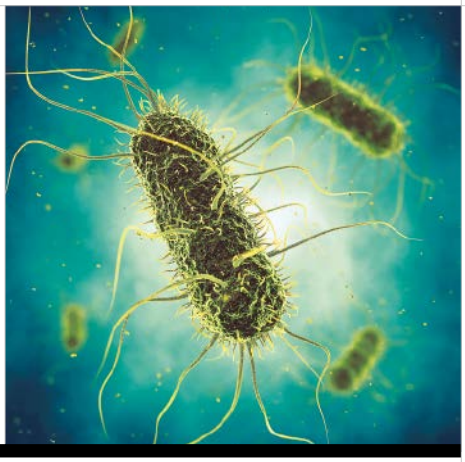
Valigra is a writer based in Harrison, Maine. Reach her at lvaligra@gmail.com.

CDC/FOODNET

Maximizing Technology Advancements in Environmental Testing

How technology is enabling the culture shift towards improved preventative control programs

BY **DAVID CLAVEAU, MSC, MBA**, **SANDRA ROGOZA**, **TED ANDREW**, AND **PHILLIP BERRY**



The Food Safety Modernization Act is now a reality as the rules' compliance dates have already started to roll out according to the published schedule. Food safety is a critical issue for all stakeholders in the production chain as the U.S. FDA is exercising its power and authority to bring federal criminal charges against companies and their management for food safety violations.

There is nowhere a company can hide from a food recall, whether it be voluntary or FDA enforced. Consumers and the legal profession are acutely aware of the food industry's product recalls in real time due to 24/7/365 connectivity of technology and speed of sharing interactive information.

As technology is increasing the food safety awareness and knowledge of consumers, it is also improving the food industry's ability to ensure that the food it provides is wholesome and safe. There are tremendous advancements in various technology platforms to support the food safety process at all stages throughout the production chain. These technologies range from enhancing "time-to-results" and accurate pathogen detection, supporting a company's Hazard Analysis and Critical Control Points and Hazard Analysis Risk-Based Preventative Controls plans, streamlining the audit process, delivering and monitoring continuous improvement on food safety education for employees, and accurately documenting food and supplier traceability, to name a few.

In particular, new technologies are now available to better monitor foodborne pathogens onsite and there are no excuses for processors not to improve their overall processing environment. All processors can start by introducing small changes in their food safety program that includes using better, more nutritive sampling devices, better performing enrichment media, and better detection methods. The ROI is almost immediate and results in improved process control, longer-term sanitation cost reduction, better production efficiency, and, most important, lowering the risk of releasing contaminated products to the market that could result in pathogen outbreaks.

Faster, Better Enrichment Method

One of the biggest and elusive culprits in food safety management is the environmental presence and growth of pathogens, such as *Listeria monocytogenes* or *Salmonella spp.*, in the processing or manufacturing facility. Environmental testing for microbiological contaminants is a key component of hygiene monitoring and risk characterization practices utilized across diverse fields of application. When selecting a detection method, a sensitive procedure is necessary as the target pathogen numbers are very low and more likely to be injured after going through heat stress,

WORDS OF WISDOM

"Even if you are on the right track, you will get run over if you just sit there."

—Will Rogers

cold stress, dehydration, starvation, etc. These injured bacteria can be incapable of growth because of structural or metabolic damage resulting from an underestimation of the true population of viable cells given false-negative results. They also become sensitive to selective components present in enrichment broth to which they normally show resistance. This could worsen when using a highly selective media because the inhibitory ingredients comprised in the formulation are optimized for the growth of populations from samples rich in nutrients and can be highly damaging for organisms adapted to low-nutrient conditions, such as the ones present on a surface. In this situation, some cells of the stressed bacterial population will not initiate growth while others will show a longer lag phase than healthy cells due to repair time. The resulting consequence is a real risk of not reaching the bacterial concentration for the detection of the pathogens within the enrichment duration. This explains why it is challenging to obtain

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appropriate enrichment conditions to provide a balance between recovery of the desired organism while avoiding the overgrowth of competing organisms.

When selecting an enrichment broth and enrichment conditions, it is important that the method is developed taking into consideration the complexity of the samples to enrich and the morphology state of the target pathogens. A nutritionally rich, semi-selective broth that supports the use of an enrichment technique is desired to improve and accelerate the recovery of stressed cells in a variety of samples. Enrichment times may vary based on the performance of the media in resuscitating weak or injured cells as well as the detection capabilities of the test assay in complex environment surfaces. Also, when making a decision to use any media, it is important to confirm that the medium has been validated to work with the desired test assay to lower the probability in obtaining false positive or negative results. Other parameters that are important to know are the specificity and the sensitivity of the media and the detection system.

Some of the features to look for when selecting an enrichment media are the ability to combine a nutritive base with the necessary ingredients to improve cell resuscitation and optimized selective agents to efficiently inhibit competing flora without affecting the growth of the target pathogen. These properties confer an important growth advantage when other bacteria are present in the samples taken from an unclean environmental surface. Furthermore, it is proven with validation studies that the enrichment time could be cut down by several hours when applying the right materials and growth conditions. An example of an enrichment media with these advantageous properties is FoodChek Systems Inc.'s ACTERO Enrichment Media developed for a single-step recovery and enrichment of stressed pathogens potentially present in environmental samples and in low quantities. This method allows for obtaining results in as little as 18 hours of enrichment for the detection of *Listeria spp.* on various surfaces and is reduced to 14 hours for *Salmonella spp.* Thus, it can be easy to integrate a robust environmental testing program based on next day results while ensuring the right food safety control.

Choosing the Right Test Technology

The surveillance and monitoring of pathogens in environmental surfaces should also be based on reliable and efficient detection technology that reinforces the effort to effectively prevent and control contamination. Several commercially available rapid methods using immunology-based assays or nucleic acid-based assays have been developed and validated that can now deliver reliable results within a few hours to a day. Rapid technologies are perceived as good value because they are accurate, easy to use, and faster than cultural methods. However, not all pathogen detection methods are the same and it can be easy to loose track of which technology best serves your environmental surface and food sampling. All have certifications of varying degrees, but practical, real-world performance offers a glimpse into some significant differences. These differences were not truly exposed in the past but now, in today's environment, may pose significant risk. For instance, while false positives are often focused on or attributed to a lack of culture, very few explore what the false negative risks may be since negatives are rarely cultured even during validation. These false negatives represent potential risk, hidden risk, and now a recall, legal, and financial risk. To avoid these risks, the processing with in-house testing capabilities or external service laboratories should consider many parameters when choosing the most acceptable method, or a combination of these methods, for their needs. The main parameters to examine when deciding to invest in testing technology are accuracy, precision, detection limit, ease-of-use, the nature of samples, cost acceptability, laboratory space, training of laboratory personnel, and quality of services after sale.

Implementing fully automated instruments that enhance the accuracy, speed, and efficiency of food safety testing through the detection of molecular pathogens, including *Listeria*, *Salmonella*, *Escherichia coli*, and other organisms potentially found in environmental and food sample contamination episodes, supports the business case of using innovative detection technology. Systems that are easy-to-use and incorporate advanced features minimize the complexity of the testing processes. Technologies that provide unparalleled scalability and reliability allow processors with in-house labs or service laboratories to meet the increasing demands of today's testing environment, as well as those of the future. An example of this are assays that target ribosomal RNA, and can also detect messenger RNA and DNA, providing the versatility of using the same technology for other nucleic acid testing applications. The combined power of technologies that these types of instruments use delivers a fully automated, single-protocol assay with reduced enrichment times and superior sensitivity. One such technology is Roka Bioscience, Inc.'s Atlas System that is based on this accurate molecular detection.

Bottom Line Benefits

Considerable progress is being made to shorten "time-to-results" of detection methods while maintaining or increasing sensitivity and specificity for detection of various pathogens, such as *Listeria monocytogenes*, *Salmonella*, and *Escherichia coli*. When combining the right sampling device with the latest technology in performing enrichment media and an accurate detection system, it is possible to reduce the "time-to-results" without compromising accuracy, to have higher throughput to maximize operating efficiencies, and to obtain test results within a production shift while improving the efficiency and efficacy of the processors' sanitation program. Embracing the latest technologies in pathogen testing also enables food processors and manufacturers to liberate their products faster and deliver fresher foods in the marketplace, and improve on protecting human and animal health. Additional research and development by media and test kit manufacturers continue to bring innovation and improvements to the detection methods available in the marketplace and help food processors protect their brand, management, and customers. ■

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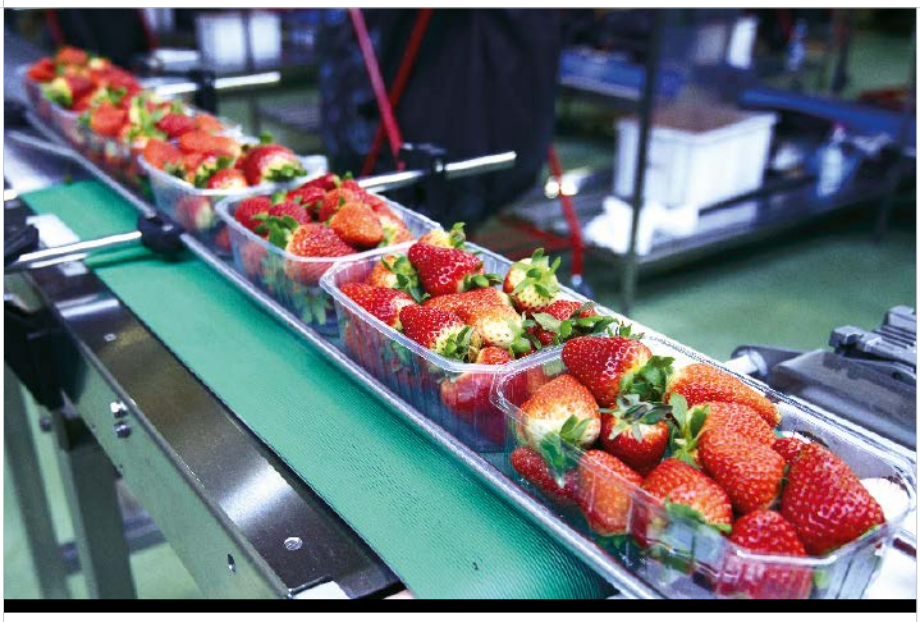

Verify Your Cleaning and Sanitation

A robust verification program combines visual inspection, microbial enumeration, and ATP detection to mitigate the risk of cross-contamination with pathogens and spoilage organisms

BY **CARI LINGLE**

Microbial contamination not only relates to the presence of pathogens but also to spoilage organisms, such as *Pseudomonas* or lactic acid bacteria. Early spoilage and product quality are increasingly becoming a blemish on a brand's reputation. Brand reputation, financial impact, and citations by regulatory agencies are at the core of the problems that occur when cleaning and sanitation is not effective in a food processing or manufacturing facility.

Through proper cleaning and sanitation, many biological risks can be prevented and controlled. In order to confidently state that a cleaning and sanitation operation was conducted successfully, the process should be verified on a regular basis. Choosing appropriate methods and relevant test points, determining an adequate sampling frequency, and analyzing the data collected over time, are all critical elements of a sound sampling, testing, and monitoring plan. Reliable data is derived from quality instruments or test kits that are routinely calibrated and tested for accuracy, and to eliminate human variability, individuals collecting the samples must be properly trained.

For as long as these concepts have been known in the industry, many methodologies have emerged in the test kit market for verification of cleaning and sanitation as a part of an environmental monitoring program. Each method brings value to an environmental monitoring program, but choosing the right tools is key.

Visually Inspecting

Visual inspection is a longstanding method and allows for a big picture assessment of the equipment and surfaces. It simply means visually evaluating a piece of equipment or plant floor location with a flashlight or blacklight. This can be useful to find the buildup of foodstuffs that were missed during cleaning as well as discovering damaged equipment. Documentation of a visual inspection can be beneficial when assessing other data and determining trends in sanitation. For example, if the wear on a piece of equipment or part is progressing over time, maintenance can be done before a serious problem occurs. Although it has benefits, visual inspection has several limitations. It is a subjective and imprecise means of verifying proper cleaning. More importantly, even if a surface appears immaculate with no apparent residue, this does not mean it is. Visual inspection cannot ensure that all of the food residue from the previous run has been cleaned away or that a sanitizer effectively reduced the microbial level on the surface.

Microbial Enumeration

Another enduring tool in an environmental monitoring plan to verify cleaning and sanitation is microbial detection through direct enumeration by a microbiological medium. This includes not only pathogens but indicator organisms as well. Currently in the industry there is great focus and importance placed on pathogen detection, however, screening for indicator organisms is also important. Understanding the trends and harborage areas of spoilage organisms to help target cleaning and sanitation efforts can increase product quality and perhaps even lengthen the shelf life of a product. The main limitation of microbial detection through traditional methods is the amount of time it takes to obtain results, especially when compared to other methods.

Before the sample reaches the microbial enumeration medium, it must first be successfully collected and also released from the collection device. Not all materials used as collection devices have the same efficiency in recovery. It is important to choose the best collection device material for all surface types being tested and ensure that the material is biocide-free. According to "Principles of Microbiological Troubleshooting in the Industrial Food Processing Environment" edited by Jeffrey L. Kornacki, when choosing the proper collection device, the size and shape must be appropriate for the area or surface being tested.

A swab works best in crevices and small areas that may be difficult to clean. However, due to their small size, swabs are

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not very sensitive when sampling large areas and can easily be impeded in areas with a heavy soil load. Pre-moistened sponges provide greater sensitivity when sampling large, flat surface areas. They also allow for greater pressure to be applied to help pick up microorganisms that have strongly adhered to the surface either by soil or their own matrix of sugar and proteins. Direct contact of a media to a surface is sensitive and works well on flat surfaces, but not as well in small spaces or gaps.

ATP

The most common rapid approach used in many facilities to assess sanitary conditions post cleaning and sanitation before starting production is measurement of levels of adenosine tri-phosphate (ATP) on surfaces or in rinse water (e.g., closed systems). Within the last several years, the decreasing size and time to result of ATP systems have made them an indispensable method for verification of cleaning and sanitation. Most ATP systems on the market are simple to use and efficient. They provide an indirect overall estimation of microbial contamination and residual organic matter that may still be present to assess the cleaning and sanitation efforts.

Instruments used for the detection of ATP, or luminometers, establish a correlation between light emitted from a bioluminescent reaction proportional to the amount of ATP present, expressed as Relative Light Units (RLU). Determination of pass/fail thresholds for ATP detection should be based on baseline values representing acceptable clean conditions. If the ATP level for an area or surface is greater than the allowable limit for that location, it can be cleaned and sanitized again before restarting production is allowed. In contrast, if using a microbial culture method, results are not known until at least 24 hours after production has begun. The rapid results offered by an ATP method allow for more immediate corrective action than most methods. As with the previously mentioned methods, it is equally important to understand the limitations and functionality of any ATP detection system being used, including but not limited to, potential food or sanitizer interference.

Choosing a luminometer is not a decision that should be taken lightly, as it will be a critical component in verifying that a facility's cleaning and sanitation procedures are effective. Firstly, the system needs to be sensitive enough to detect low levels of residue or contamination. The components on the luminometer should be of good quality. In particular, the apparatus that detects the light emitted from the reaction of the ATP, luciferin, and luciferase should be best in class. For example, a photomultiplier detector may be more expensive but is considerably more sensitive than a photodiode. Capable of detecting small amounts of light emitted from the reaction, a photomultiplier is more sensitive given that it multiplies the current produced by the incident light by a million times. Instruments with a photodiode rely on the swab formulation to strengthen the light signal to get a better reading. However, users must be quick to place the swab into the instrument after exposing the swab to the chemistry containing the luciferin and luciferase enzymes. There is a significantly shorter window of opportunity to analyze the swab as the increase in enzymatic activity reduces the amount of time that the light is emitted from the reaction.

Secondly, results should be repeatable and consistent from swab to swab, analyst to analyst and day to day. This is particularly important when monitoring data over time and looking for trends. Having to conduct extra cleaning or missing contamination due to variance from the instrument or swab is not an efficient way to verify cleaning and sanitation. Moreover, many instruments can have differing results due to temperature changes or even the position the instrument was held in during the reading. Choosing an instrument that provides sensitive and consistent results at a wide range of temperatures is essential. This is especially true if part of the environmental monitoring plan includes cold rooms. As a measurement of repeatability, the coefficient of variation expressed as percentage can be calculated for an ATP detection system. The lower the coefficient of variation, the more repeatable results that can be obtained from the method.

A comprehensive but simple-to-use data management system can easily upload or import data from the ATP instrument and can be a beneficial tool to help with test planning and data trending. Documentation is a key element of managing compliance with preventive controls, and having a system that can easily display the data in a way that is useful can improve cleaning and sanitation over time. In a well-established environmental monitoring program, it may not be necessary to sample every test point before every startup. A randomization algorithm is helpful to enable more efficient environmental monitoring without bias from operators. Monitoring trends and data can be accomplished even more effectively if the system allows for recording not only the ATP values but also other criteria such as visual inspection results. This allows for a quick view of a more complete picture rather than just one component.

It is beneficial to note that ATP detection systems detect one thing—ATP. Determination of whether ATP detected on a surface has come from the food or microorganisms or a combination of both cannot be deciphered by a luminometer. If it is a combination of both microorganism and food, it is impossible to know what proportion of the ATP being detected comes from the food or microorganism. Additionally, there is no correlation between RLU values and the number of microorganisms present on a surface. There is considerable variation in cellular ATP levels, particularly between species of microorganisms.

In Summary

Visual inspection, microbial enumeration, and ATP detection all have a role to play when verifying cleaning and sanitation. Visual inspection allows for the quick, simple detection of heavily soiled surfaces. Microbial detection can help determine the source of product contamination, identify niches harboring specific classes of microbes missed during cleaning and sanitation, and track where microorganisms may be going next. ATP bioluminescence systems provide a rapid, actionable result if cleaning and sanitation did not successfully remove foodstuffs or microbes. The key to link all of these tools together is to analyze the data and monitor for trends to gain a true understanding of the large picture in regards to microbial control in a facility. ■

Lingle is senior microbiologist for global technical service at 3M Food Safety. Reach her at cklingle@mmm.com.

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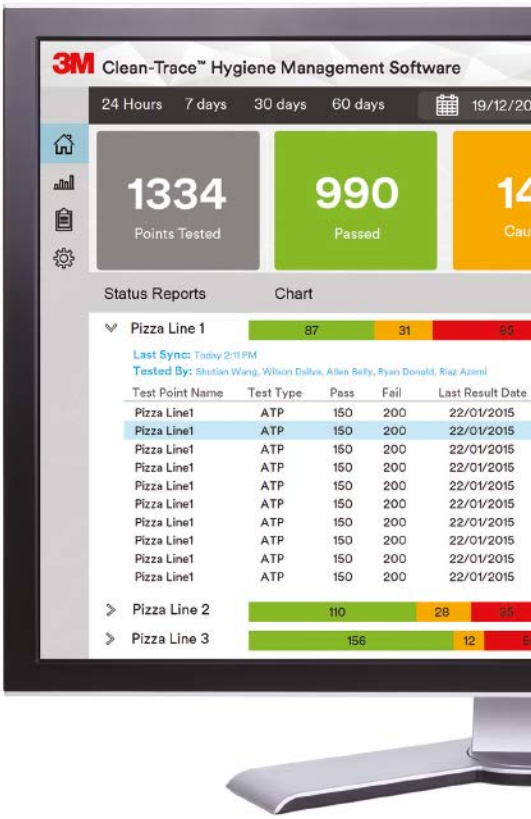

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Biosecurity FAQs

Answers to how gas-based sterilization helps food processing facilities manage decontamination issues

BY **JOHN MASON**

Q: Why are biosecurity-related incidents on the rise in the food industry despite so many layers of protection and increased regulatory compliance requirements?

A: It is likely that in many cases the contamination has always been there, so it can't be said for certain that contamination itself is on the rise. The industry is detecting contamination more often than it did before because it has higher detection capabilities and higher frequency of testing than was previously the case.

However, pesticide residuals are now more tightly regulated. It is possible that the industry is seeing more organisms come into facilities or these organisms could become resistant to the conventional sanitation approaches used pre-processing. The drive towards organic and the drive towards the fresh-to-market concept also contribute to a higher potential for bacterial contamination because the products are less processed.

Regardless of the reason or reasons, now that companies are discovering contamination in their facilities, they have to address it. In addition, if they haven't discovered contamination, that doesn't necessarily mean that they are contamination-free, or couldn't become contaminated tomorrow or the day after.

Q: What are the most vulnerable entry-points pathogen contaminants can penetrate food processing and manufacturing plants?

A: Pathogens can penetrate either with the product being processed or with the people associated with it. People do carry pathogens. That is why, for example, hand sanitation and all the prepping of personnel before handling the product are so important.

The product is vulnerable to cross-contamination during the production stage. Improper wastewater or fertilization methods of the product can happen at the production facility it originated from. Cross-contamination can also occur during the transportation stage. Trucks may have been contaminated either coming in or going out of facilities.

Cross-contamination can also occur in the plant itself in the form of latent materials, such as dust or dirt, that go undetected until sampling a specific location and looking for that kind of airborne contamination to mitigate it before it becomes a problem. For example, in dry storage facilities, dust can be transported in an airborne fashion to the commodity being processed.

It is probably not possible to monitor, or even know every possible entry point, or, at a minimum, do so in a cost-efficient manner. That is why periodic, proactive decontamination is emerging as a best practice for processors.

Q: What are the limitations of the prevalent sanitation practices in use during sanitation cycles? Are there emerging or alternative methods that address these limitations?

A: Currently, the processing industry utilizes liquid-based sanitation methods, which are limited in their penetration, ease of coverage, and degree of sanitation effectiveness. The contaminated area is isolated and treated along with people working in the area. What happens if there's a big problem, such as *Listeria* or *Salmonella*, but you cannot actually find it? Therefore you do not know which area/surfaces to isolate and treat.

Gas-based sterilization solutions directly address this limitation. Gas inherently goes everywhere. It penetrates everything and when properly applied there is not a spot that is left untouched, including all the places that are otherwise hard to get to, such as air ducts or underneath the cutting boards. Gas-based deployment decreases the risk of human error (for instance, missing a contaminated area that can be very small in size and still provide a significant contamination threat) and ensures consistent and correct application throughout the facility by penetrating all types of surfaces, including the porous ones. Unlike liquid sterilants, gas does not move contaminants around. Gas-based sterilization is also easier and faster to apply while ultimately being less expensive than manually wiping down thousands of square feet of processing floor space. It is for this reason that gas greatly facilitates proactive and preventative sanitation in addition to its advantages in reacting to a contamination event.

Finally, sterilization should really mean, "I have eliminated 99.99 percent of every piece of dirt or dust that could

Biosecurity Measures in Poultry Production

The Journal of Applied Microbiology's recent article, "Control strategies against *Campylobacter* at the poultry production level: biosecurity measures, feed additives, and vaccination," describes the control strategies implemented during the past few decades in primary poultry production. The review discusses the implementation of biosecurity and hygiene measures, as well as the immune strategy with passive immunization and vaccination trials.

According to the authors, new efforts are needed to test *in vivo* components, such as new nutritional additives, vaccine antigens, or a combination of both, at experimental and farm levels, with biosecurity measures maintained throughout the poultry rearing process.—*FQ&S*

be a contamination threat." Sterilization achieved by gas provides a higher level of sanitation and decontamination than other methods. BioWALL proved that by decontaminating the Senate Office Building, NBC, the National Enquirer, and various post offices infected with Anthrax in 2001. There was absolutely zero margin for error in that environment—any residual contamination would likely have resulted in death for those reinhabiting those buildings.

Q: What specific preventive measures should quality assurance and food safety managers and food plant managers undertake to manage risks in their own facilities?
A: Continuously step up sampling methods and look at airborne samples to detect what's being spread around. Even though you did not have a recall, it does not mean that there are no latent threats that could potentially develop into a much bigger issue.

Use a gas-based approach during the required weekly or monthly high-level sanitations and use the liquid-based approach during the daily one. Facilities are required to conduct weekly or monthly high-level sanitations. Those would be the best times to use a gas-based approach to eliminate all the pathogens that could be working and not give them a chance to build up.

And go into critical control mode during routine testing. If areas have been identified as known problem areas, you should constantly test those areas to preserve a contamination-free space. Do not just "administratively pass tests" by sampling for physical contaminants. Challenge those routines by adding known very-resistant pathogen surrogates and make sure that they are killed.

Q: Why does preventive biosecurity planning matter?
A: Look at the cost of a potential risk and ask yourself how much is your brand worth to you, what are you doing to protect it, and what is the degree of "surety" you want that there isn't any contamination in the plant?

Barriers are needed all along the way. It is the segmentation of those barriers that provides the protection needed to safeguard the quality of your product, your reputation, the overall costs of recalls or production downtime, and public health.

The industry needs to move toward protection and prevention, and away from response.

Q: What will food processing biosecurity look like in the next two or three years?
A: Experts within the food industry are currently being tasked with solving the questions posed here. As a result, the industry will continue to advance its efforts and safeguards to protect brands and consumers. Additionally, the increased regulatory presence will help drive adaptation of technologies. There are solutions to these issues—it is about providing the industry with comprehensive tools to address them. ■

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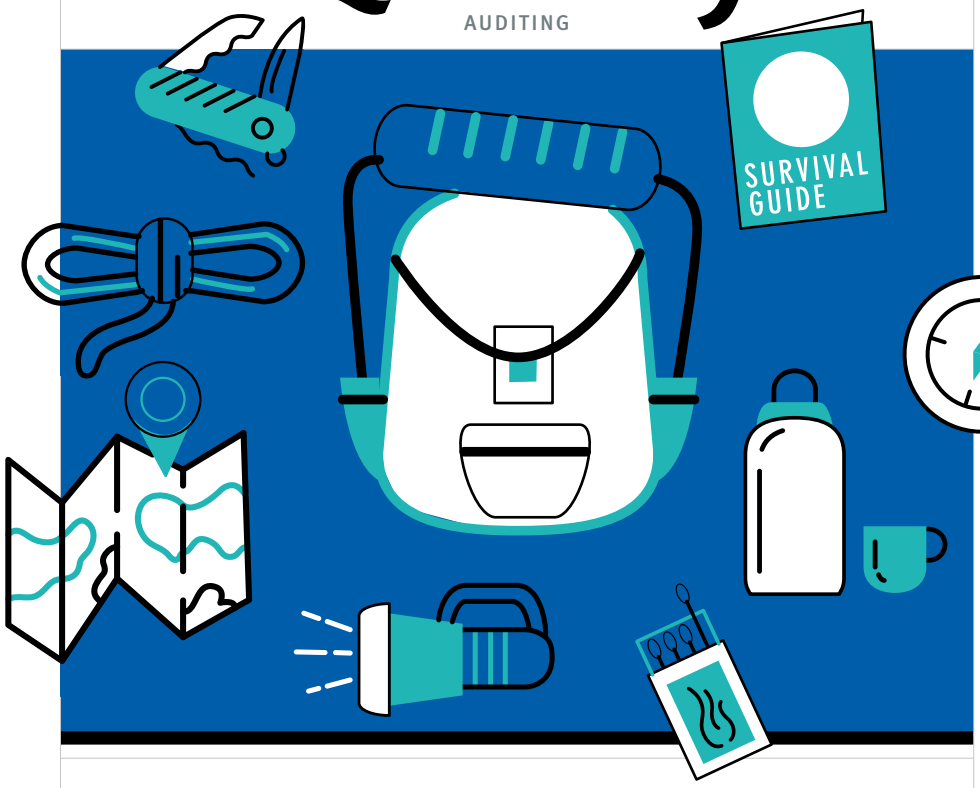
Quality

AUDITING



Survival Guide to Auditing

An auditor's perspective on maintaining GFSI sustainability and avoiding common mistakes during inspections

BY **JEFF CHILTON**

Without a sustainable management system, the results of your hard work toward meeting the requirements of SQF, BRC, or FSSC 22000 certification could begin to degrade between routine audits. With so much at stake and competing demands from regulators, customers, and consumers, securing a sustainable Global Food Safety Initiative (GFSI) system can be a challenge.

The following guidelines can help your company stay audit-ready 24/7 while continuing to advance your GFSI systems.

Robust GFSI Internal Audits

GFSI standards require an internal audit of the entire system at least once per year. Prudent companies manage internal audits on a set schedule. Start by dividing sections of GFSI code, and then schedule an internal audit of each section on a monthly or quarterly cadence. Be sure that your schedule enables you to cover the entire code over the course of the year. By auditing smaller sections of the code on a more frequent basis, internal teams can take more time to assess programs, analyze records, and review facility conditions as necessary.

It is important for internal auditors to be properly trained on what to look for, how to record results, and how to follow up on possible corrective actions needed. As a best practice, have a third party complete an internal audit of your system prior to your recertification audit. External resources will provide an objective view and assure all programs are at their best.

Detailed Plant Inspection Internal Audits

In addition to the GFSI system audits, detailed plant inspection audits should be conducted based on risk. This typically includes monthly inspections of processing audits. These inspections include assessments of Good Manufacturing Practices, product handling, and facility condition. Detailed plant inspections and internal audits help promote continual compliance with GFSI standards.

Verification/Validation of Prerequisite Programs

GFSI standards require all prerequisite programs, such as sanitation, maintenance, calibrations, pest control, and others, be verified and validated at least once a year. The verification process should include a review of the written food safety program, records and supporting evidence, and documented plant inspections. The validation process should include a review of test results, customer complaints, non-conforming products, and other relevant information to ensure the program is achieving and maintaining the intended control over identified hazards. Prudent companies set schedules to verify and validate a certain number of programs each quarter.

Automated Program Management and Recordkeeping

Companies should seriously consider taking advantage of automated food safety and quality management systems to sustain GFSI compliance. Companies must adopt 21st-century methods and technology to provide QA departments with the ability to manage the massive number of programs and the amount of critical documentation associated with food safety and quality assurance systems. An electronic, cloud-based system can save time and make complex recordkeeping much simpler. Companies often already have systems for enterprise resource planning (or ERP), preventive maintenance, and master sanitation schedules. QA departments should employ similar tools to organize and manage food safety programs, maintain records, and drive internal auditing efforts.

(Continued on p. 38)

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Comprehensive Food Safety Plan Reassessments

Annual food safety plan reanalysis or Hazard Analysis and Critical Control Point plan reassessments are not completed by simply changing the date on a cover page—something auditors see all too often. Food safety plans must be kept up to date throughout the year. Be sure the plans incorporate any changes related to new ingredients, finished products, or equipment. During the plant's annual review process, the entire food safety system should be reviewed and audited to verify that the plan is being followed as intended. The plan must be written correctly and validated with testing to demonstrate control over identified hazards.

When completing the reassessment process, review all written programs for accuracy. A detailed plant inspection and audit of critical control points or preventive controls must be performed to show compliance with the food safety plan. Finally, confirm the consistent implementation of your food safety plan with a review of all related records from the past 60 days. Take the time to scrutinize whether or not adequate corrective actions have been taken where needed. Once all this information has been gathered, submit a reassessment report with a complete summary of all changes.

Effective Management Reviews

GFSI standards require regular management reviews. These management reviews must consider the GFSI policy manual, internal and external audit findings, customer complaints, and corrective actions. As a best practice, management reviews should happen quarterly. During that time, assess the results of the GFSI system with a trend analysis then compare current results with prior periods. This helps identify areas that need to be addressed immediately to repair deficiencies or negative trends, as well as areas for continuous improvement. Management reviews must engage senior leadership so they are aware of the GFSI system performance and can provide additional resources as necessary.

Coordinated Change Management

Products, formulations, equipment, and other assets change rapidly in most manufacturing plants. There must be a coordinated change management process to assure these changes are communicated to all necessary parties. Be sure that modifications are properly documented, verified, and validated in the GFSI system, and confirm all changes have been fully implemented throughout the company.

Positive Food Safety Culture

Continuous audit readiness cannot be achieved without a positive food safety culture. Top management must share vision and commitment. All employees must be trained on not only *what* to do, but *why* they need to do it. This approach solidifies employees' commitment to follow programs and handle products properly all the time, whether there is anyone watching or not. Perform food safety culture assessments routinely to measure and drive continuous improvement. ■

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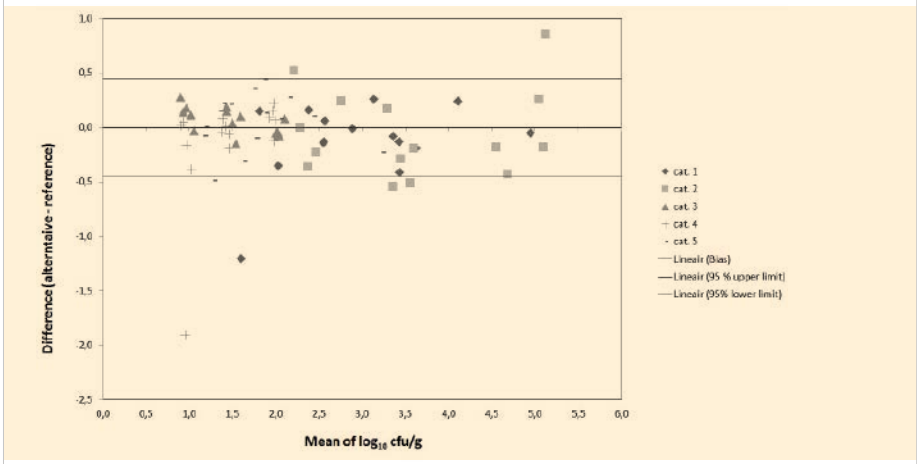
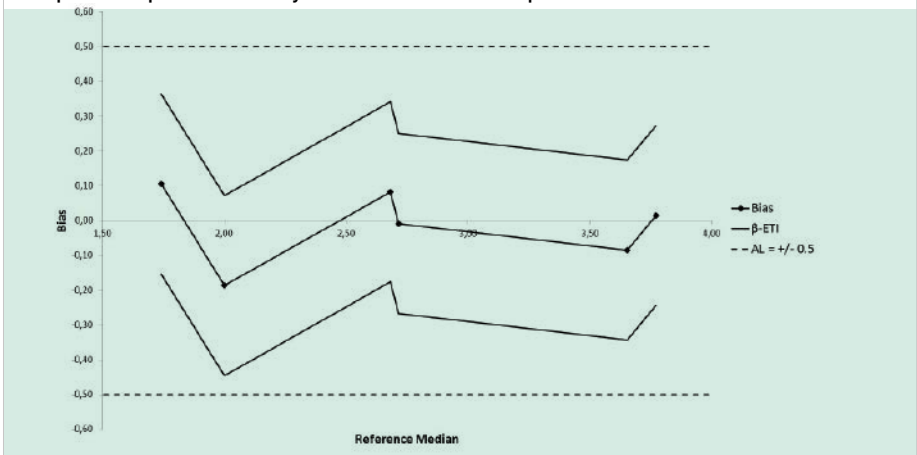
Graph 1. Example of the Bland-Altman plot for the validation of quantitative methods.



Graph 2. Example of the Accuracy Profile for the validation of quantitative methods.



Revised ISO 16140

Changes for validating alternative methods in microbiology of the food chain

BY **PAUL IN 'T VELD**, **DANIELE SOHIER**, **LAURA MOUT**, **GWÉNOLA HARDOUIN,** AND **BERTRAND LOMBARD**

The revised version of the standard ISO 16140 was published in June 2016 as ISO 16140 Part 2, *Protocol for the validation of alternative (proprietary) methods against a reference method*. This standard is describing the validation of alternative (proprietary) methods compared to a reference method, in the field of microbiology of the food chain. This field is covering the whole chain of food production, from primary production, feed, environment of food processing and handling, storage to end-products. ISO 16140:2003 has been used successfully over the years resulting in more than 100 validated alternative methods that are commonly used by routine testing laboratories. This standard is a common European and International Standard, developed in the framework of CEN (European Committee for standardization) and ISO (International Organization for Standardization) cooperation agreement and it is referenced in European legislation (Commission regulation No. 2073/2005 on microbiological criteria for foodstuffs) as the procedure to validate alternative methods.

The revision of this standard was conducted under the responsibility of Subcommittee ISO technical committee 34/Subcommittee 9 (ISO/TC 34/SC 9), *Food Products—Microbiology*, and by its Working Group WG 3, *Method validation*, in cooperation with CEN/TC 275/WG 6, *Microbiology of the food chain*, to deliver a common standard. WG 3 has not only been responsible for drafting the new ISO 16140-2, but is also drafting other standards that are relevant for validation and verification of methods in microbiology of the food chain.

Why a Standard for Validation?

Testing of food for the presence or level of pathogenic microorganisms and hygiene indicators (mostly bacteria, but also yeasts and molds, viruses, and parasites) is crucial for ensuring food safety. Food producers are testing their products based on legal requirements, client specifications and/or as a way to control/check their production process. There is a strong need for analytical methods that will give a result in a very short time but also whose performances are assessed. The standardized methods developed by ISO/TC 34/SC 9 and CEN/TC 275/WG 6 are mainly based on culturing techniques that might take a long time before providing the end result of the test method. This is (partly) due to the fact that the standards cannot use proprietary components in their methods and, in general, prefer methodologies that can culture the target organism so further typing can be done, e.g. for traceability. This is why the methods are regarded as reference methods. In practice, many alternative methods are developed on a commercial (proprietary) basis and are widely used for several reasons. These reasons are, for example, the time to provide the result, easiness of use, and total cost per sample, including human resources. However, it is not known whether the al-

(Continued on p. 40)

SOURCE: ISO

(Continued from p. 39)
ternative method will give similar results to the reference method. This issue was already noticed in the early 1990s. This lead to a EU funded project, named MicroVal, which started in 1993 and was the basis for the publication of the first version of ISO 16140, which was developed under CEN lead.

Most Important Changes

ISO 16140-2:2016 is the successor of ISO 16140:2003 and the work for the revision started in 2006 as the existing standard lacked, amongst others, objective criteria to validate the methods as fit for purpose.

The principle for both versions is still the same; a protocol describing the validation of qualitative methods and quantitative methods, which require different performance parameters. Both types of studies consist of a method comparison study, carried out in one "expert" laboratory, and an inter-laboratory study led by this expert laboratory. Performance parameters are selected, each with a definition, an experimental design, calculations, and interpretation. The details for conducting the studies and the interpretation of the results have been substantially changed for certain aspects.

Method comparison study for qualitative methods. The first important change is the introduction of the concept of a "paired" and an "unpaired" study. A paired study is a study where both the reference and the alternative methods use the same first step in the enrichment protocol, e.g. pre-enrichment of *Salmonella* in Buffered Peptone Water (BPW) for 16 hours to 20 hours at 37 degrees Celsius. In case of an unpaired study, the first step for the reference and alternative methods are not identical, e.g. the use of a specific enrichment broth other than BPW for the alternative method. In this case separate test portions (from the same sample) need to be tested for the reference and the alternative methods. This seems a technical change but it has a major impact on the interpretation of the results. In a paired study, it is easy to determine what is a false-negative result (= result that was positive by the reference method but negative by the alternative method). When the reference method gives a positive result the alternative method should also have a positive result as it is proven that the sample contains the target microorganism e.g. *Salmonella*. But in an unpaired study, there is no direct link anymore between the result obtained with the reference and alternative methods as they use different test portions. This is especially the case when the contamination level of the samples is very low. For qualitative methods the level of contamination should be very low in order to demonstrate that the methods work as intended. The heterogeneity caused by the low levels leads to differences between test portions as some test portions will not contain the target organism anymore and thus cannot be found positive.

For the interpretation of results, a new concept is introduced as well. The evaluation is founded on so called Acceptability Limits (AL). These ALs are based on evaluation of previous validation studies and expert opinion. They are not based on formal statistical tests, like the χ^2 test in ISO 16140:2003. This test was in practice not capable of detecting differences between the reference and alternative methods that were, according to many microbiologists, important differences. The ALs are based on the number of positive and negative deviations observed in the validation study, and maximum acceptable values for paired and unpaired studies are determined.

Another important difference compared to ISO 16140:2003 is the introduction of the Relative Level of Detection (RLOD) concept. In this new concept, the two methods are compared using the same (artificially contaminated) samples. The level of contamination should be very low so that not all samples tested will be positive for the target organism. By testing many replicates (20) at this low level, differences in the number of positives found by the reference and alternative methods can be observed. The observed difference is then compared to a preset AL. The actual level of contamination of the samples is not used in the evaluation of the data because the accurate determination of a very low level of contamination (sometimes lower than 1 colony forming unit per test portion) is difficult to determine. The experimental design of the RLOD study is also fully in line with the Probability of Detection used by AOAC International. The statistical analysis of the results is however different, being based on a generalized linear model developed by WG 2, *Statistics* of ISO/TC 34/SC 9.

Quantitative methods. The "relative trueness" study replaces the former "linearity and accuracy" study. The experimental design of this part of the validation study is not changed compared to ISO 16140:2003, but the evaluation of the data is. Linear regression is no more carried out but the data are plotted in two different ways, as a scatter plot and as a Bland–Altman plot. The scatter plot gives an impression of the linearity of the results. In the Bland-Altman plot (see Graph 1 on p. 39) the difference between the alternative-method ($\log_{10}$ transformed) result and the reference-method ($\log_{10}$ transformed) result is plotted for each individual sample. This plot also contains the data points for samples where one of the two methods gave a result that was outside the quantification limit of the method (e.g. counts lower than 10 on a plate). Rules for the quantification limits of reference methods are described in ISO 7218, *Microbiology of food and animal feeding stuffs—General requirements and guidance for microbiological examinations*. Based on the two plots, the data are interpreted and visually outlying results should be investigated in order to explain the cause of this variation.

Another main change is the introduction of the "accuracy profile" study. This study is a combination of testing for bias and precision. The calculations are based on a tolerance interval and evaluation of the data is done using an AL of 0,5 log in the general case. Results are graphically presented as in Graph 2 (on p. 39). Results are represented by the middle curve, with below and above the two tolerance intervals and AL are represented by the two fixed dotted lines below and above the observed data.

Transition to ISO 16140-2:2016

ISO 16140-2 is substantially different from its predecessor. This will certainly influence the way alternative methods will be validated in the short future but what about the existing validated alternative methods? Publishing a new and improved standard does not necessarily mean that the old way of validation was inappropriate and that the methods validated accord-

ing to the former version of the standard are not valid anymore. Therefore, WG 3 has drafted a document endorsed by ISO/TC 34/SC 9, called Guidance on the Transition from ISO 16140:2003 to ISO 16140-2:2016, in order to guide mainly the validation/certification organizations, and as well other involved parties (such as expert laboratories, method developers, regulation bodies) on the implementation of the new ISO 16140-2. This document is an internal ISO/TC 34/SC 9 document, but has been sent to various organizations that are involved in validation of methods, e.g. AFNOR Certification, MicroVal.

ISO 16140-2:2016 has already been used in several validation studies that have been recently finalized or are still in the validation process. No major concerns have been encountered yet with the use of the new validation standard.

Validation in Microbiology

As briefly noted earlier, the work of WG 3 is not limited to ISO 16140-2. This group has currently developed two other standards, being ISO 16140-1, *Vocabulary*, and ISO 17468, *Technical requirements and guidance on establishment or revision of a standardized reference method*. They have been published at the same time as ISO 16140-2.

In addition, WG 3 is currently working on four other parts of the ISO 16140 series:

1. Protocol for the verification of reference and validated alternative methods implemented in a single laboratory (Part 3 of ISO 16140);

2. Protocol for single-laboratory (in-house) method validation (Part 4 of ISO 16140);

3. Protocol for factorial inter-laboratory validation for non-proprietary methods (Part 5 of ISO 16140); and

4. Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing (Part 6 of ISO 16140).

Part 3, method verification, will especially have a strong impact on all laboratories carrying out analyses in food chain microbiology. Method verification is the study that a laboratory needs to conduct in order to demonstrate its competence in applying a validated method in its own laboratory. Parts 4 and 5 focus on in-house method development/validation and offer new opportunities for laboratories operating in food microbiology testing. Part 6 will provide a technical protocol for the validation of proprietary methods for isolates confirmation, which is also a new concept. ■

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Personal Hygiene Influences Food Safety

Foodborne illness is a common, costly, yet preventable public health problem—both employees and employers need to follow through on responsibilities

BY **ANDREW WOOD**

You may ask yourself, why is personal hygiene really that important? When visiting a new restaurant or a food retail store, an employee's personal hygiene has a great influence on the perception of the stores cleanliness as a whole. Businesses in the food industry should always strive to avoid any issues related to personal hygiene. Programs and training must be in place to improve personal hygiene, which include knowledge of foodborne illnesses, employee's responsibility, management responsibility, and third-party services.

The Big 5

Let's begin with the "Big 5" foodborne pathogens stated by the CDC and the FDA. These five foodborne pathogens include norovirus, the Hepatitis A virus, *Salmonella*, *Shigella*, and *Escherichia coli* (*E. coli*) O157:H7. Other less infectious pathogens that can also be transmitted by food employees to consumers through contaminated food include *Staphylococcus aureus* (staph infection) and *Streptococcus pyogenes*.

Norovirus is a highly contagious virus that can cause symptoms such as diarrhea, throwing up, and stomach pain. About 20 million people contract norovirus each year, most from close contact with infected people or by eating contaminated food. Norovirus is the leading cause of disease outbreaks from contaminated food in the U.S. Infected food workers cause about 70 percent of reported norovirus outbreaks. Contrary to a lot of belief, hand sanitizers are largely ineffective against norovirus, which is why proper handwashing with soap and water is a necessity.

Hepatitis A is a contagious liver disease that results from infection with the Hepatitis A virus. It ranges in severity from a mild illness lasting a few weeks to a severe illness lasting several months. Hepatitis A is usually spread when a person ingests the virus from contact with objects, foods, or drinks contaminated by feces or stool from an infected person. It is a must that all employees thoroughly wash their hands and fingernails after using the restroom. Some counties in the U.S. require all food handlers to be vaccinated against Hepatitis A.

Salmonellosis, the illness caused by *Salmonella*, primarily results in a mild to severe diarrheal illness, known as acute gastroenteritis. The CDC estimates that approximately 1.2 million illnesses and 450 deaths occur due to non-typhoidal *Salmonella* annually in the U.S. Person to person transmission of *Salmonella* occurs when an infected person's feces, unwashed from his or her hands, contaminates food during preparation or comes into direct contact with another person.

Shigellosis is a diarrheal disease caused by a group of bacteria called *Shigella*. Most who are infected with *Shigella* develop diarrhea, fever, and stomach cramps starting a day or two after they are exposed to the bacteria. Shigellosis usually resolves in 5 to 7 days. *Shigella* causes about 500,000 cases of diarrhea in the U.S. annually. *Shigella* is found in the intestinal tract of infected people, and is spread by eating or drinking food or water contaminated with the bacteria.

E. coli is a large and diverse group of bacteria. Although most strains of *E. coli* are harmless, others can make you sick. Some types of *E. coli* can cause diarrhea, while others cause urinary tract infections, respiratory illness and pneumonia, and other illnesses. Still, other types of *E. coli* are used as markers for water contamination, so you might hear about *E. coli* being found in drinking water, which are

Food employees share the responsibility with management for preventing foodborne illness and are required to know the causes and prevention of these illnesses.

not themselves harmful, but indicate the water is contaminated. *E. coli* O157:H7 is transmitted to humans primarily through consumption of contaminated foods, such as raw or undercooked ground meat products and raw milk. The importance of washing your hands is just as great, if not greater than the importance of washing your hands after using the restroom.

Preventive Measures

Now what can restaurants and retail stores do to mitigate the risk? It all begins with the policies and management in place. The manager is to make certain that food employees are trained in the causes and prevention of foodborne illnesses. Employers will benefit greatly if their employees are aware of the relationship between their job, personal hygiene, and foodborne illnesses. Management should explain to all food service employees the importance of reporting specific symptoms and any diagnoses or exposures to foodborne illness. If an employee is experiencing any vomiting or diarrhea, the manager should ask the food employee to stop work immediately and leave the food establishment. The employee should return to work no sooner than 24 hours after vomiting and diarrhea have ended.

After speaking on how management can prevent foodborne illnesses, let's transition to an employee's responsibility. Food employees share the responsibility with management for preventing foodborne illness and are required to know the causes and prevention of these illnesses. They need to immediately report symptoms of vomiting, diarrhea, jaundice, sore throat with fever, diagnosis or exposure of illness caused by a "Big 5" pathogen, or an exposed infected wound or cut on the hands or arms to their manager. Food employees can work with a non-infectious condition as long as they can provide medical documentation indicating that the symptoms are from a non-infectious condition. Some non-infectious conditions include Crohn's disease (an ongoing disorder that causes inflammation of the gastrointestinal system), irritable bowel syndrome, some liver diseases, and symptoms commonly experienced during stages of pregnancy. Employees can help prevent foodborne illness by avoiding work when ill, not touching ready-to-eat food with bare hands, and washing hands frequently, especially whenever they are soiled or have touched anything that has contaminated them.

Along with foodborne illnesses, allergens can be spread without proper personal hygiene and handwashing. For example, if an employee has peanut residue on his hands while serving a customer with a peanut allergy, it can have detrimental effects. All employees must wash their hands properly before entering the workplace from a break.

Helpful Services

Once the management and employees know what to do in these situations, it is a good idea to see what services are out there to better improve food safety programs. The first step should be to look into available training and certifications. An example of a beneficial program for retail and restaurants is the ServSafe Food Handler Program, which is broken into sections. The five sections are Basic Food Safety, Personal Hygiene, Cross-Contamination and Allergens, Time and Temperature, and Cleaning and Sanitation. You must complete these sections before the assessment is available. There is an optional Job Specific section that your manager may want you to complete.

After the programs and training are in place, it can be beneficial for a third-party company to come out for an inspection. Food safety auditing companies, like ASI Food Safety, offer specific third-party audits that check your current programs and practices. During an independent audit, ASI will look at the facility's food safety practices, employee practices, programs, training, maintenance, and pest control. ASI will also ensure that associates wash hands, fingernails, and arms with liquid hand soap, followed by an alcohol-based hand sanitizer after a break or lunch. This will mitigate the risk of spreading foodborne illnesses and allergens.

Programs and training must be in place to improve personal hygiene, which include knowledge of foodborne illnesses, employee's responsibility, management responsibility, and third-party services that are offered. Improper personal hygiene can carry weight on your establishment if an outbreak is linked back to your product. Employees should be educated on the importance of personal hygiene to mitigate the risk of foodborne illnesses and allergens. Remember, one negative online review or a pathogen outbreak linked to your establishment can go a long way in today's world. ■

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Keeping Hands Clean and Healthy

Implementing proper hand hygiene protocols can help prevent norovirus outbreaks

BY **ANDREAS KLOTZ**

If food service and retail employees don't practice proper hand hygiene, they could be serving a side of norovirus with their customers' orders. Norovirus outbreaks from contaminated food in food service settings are often linked to infected food workers, according to CDC report. These outbreaks can be prevented by educating workers about proper hand hygiene on the job and making sure they stay home when they are sick.

Norovirus is highly contagious and can spread anywhere food is served, making people sick with vomiting and diarrhea. According to the CDC, about 20 million people get sick from norovirus each year. In addition to the risk of a norovirus outbreak, poor hand hygiene will lead to increased illness and can result in:

- Disruption cost and lost productivity through employee absence from work;
- Reduced employee efficiency through illness at work and lower employee morale; and
- Damage to a business' reputation.

For any organization, implementing and maintaining an appropriate hand hygiene routine is a daily challenge. Employers and facility managers have a legal responsibility to ensure that they provide a safe working environment for their employees—addressing hand hygiene is a vital asset.

Common Norovirus Carriers

According to the CDC, health departments reported 1,008 norovirus outbreaks from contaminated food between 2009 and 2012, most of which occurred in food service settings, such as restaurants, catering, or banquet facilities.

The CDC also looked at foods that were commonly implicated in norovirus outbreaks. Of 324 outbreaks with a specific food item implicated, more than 90 percent were contaminated during final preparation (such as making a sandwich with raw and already cooked ingredients) and 75 percent were foods eaten raw. Leafy vegetables, fruits, and mollusks, such as oysters, were the most common single food categories implicated in these outbreaks.

Tips for Healthy Hands

Wash hands properly and often. Apply a small amount of hand cleanser to dry hands. Rub hands vigorously together for at least 20 seconds. Scrub all surfaces, including the backs of hands, wrists, between the fingers, and under the fingernails. Rinse well and dry hands with a clean or disposable towel. Make sure to use a clean towel to turn off the faucet.

Use the right cleanser for the job. There is an ongoing misconception that a hand cleanser's performance is measured by its ability to clean hands aggressively. In actuality, most cleansers far surpass the user's actual requirements. Make sure to choose a sanitation product that takes into consideration the impact on the hands, yet is still effective for the job.

Keep cleansers accessible. The location of hand cleansers can help increase handwashing compliance. Place them where they are easy to find and enforce the importance of handwashing throughout the day.

Use gloves where required or necessary. It's not always practical to use gloves when working. Nonetheless, gloves should be used whenever possible to ensure that cross-contamination is less of a risk.

Handwashing Best Practices

Once your team learns more about prevention, pick the best-suited hand cleanser and dispensing system. Table 1 provides a quick reference guide to keep employees clean and compliant.

The appropriate products should be available and accessible to workers where and when they are required, such as food processing area entrances, washrooms, and handwashing stations.

Developing a good handwashing technique is imperative to ensure hands are thoroughly clean. Pay particular attention to the backs of the hands and fingertips as these spots are frequently missed. To limit sickness and absenteeism in the workplace, encourage the following handwashing steps:

1. Rub palm to palm;

2. Rub palm over back of hand, fingers interlaced;

Table 1. Hand Cleanser Types.

Cleansing Level	Benefits	Ideal Use
Washroom	• Many people are familiar with these general light cleansers, which can encourage handwashing compliance • Works well for general hand hygiene and is gentle on skin	• General products that successfully clean skin in offices and public washrooms, showers, and leisure facilities • Great for high-traffic facilities where effective, gentle cleansing is required for everyday dirt and grime
Antibacterial	• Antibacterial foams help to protect from infection and to prevent cross-contamination • Can remove vegetable oils, animal fats, and general dirt and grime	• Good option for washrooms and other high-traffic areas where germ and bacteria exposure can be high • Look for options rated for use in food handling environments (NSF E2*) where employees can be exposed to foodborne pathogens

**NSF International certifies food-related products and systems. Antibacterial hand soaps fall under the NSF standard E2.*

3. Palm to palm, fingers interlaced;
4. Fingers interlocked into palms;
5. Rotational rubbing of thumb clasped into palm; and
6. Rotational rubbing of clasped fingers into palm.

Workers should rub theirs hands together for at least 20 seconds; the length of humming the "Happy Birthday" song from beginning to end twice. Skin should always be properly dried to avoid risk of chapping, particularly during the winter months. Clean towels need to be available at all times—dirty towels mean exposing the skin to more dirt and the risk of infection. Ideally, single issue disposable towels should be used as communal towels can lead to contamination.

Hand Sanitizers Come in Handy

When it's not convenient to use soap and water or when soap and water are not available, it is acceptable to use an alcohol-based broad spectrum hand sanitizer that contains at least 60 percent alcohol. According to the CDC, hand sanitizers with an alcohol concentration greater than 60 percent are very effective at killing germs and can reduce the number of microbes on a person's hands quickly. However, it's important to note that hand sanitizers don't eliminate all bacteria. Washing your hands with soap and water is more effective against specific types of germs, especially norovirus. Alcohol-based hand sanitizers used in food handling environments should be fragrance-free and ideally have an NSF E3 rating (NSF International certifies food-related products and systems, hand sanitizers fall under the NSF standard E3). Gel-based products can be sticky and leave gelling agent residues on the skin. Foam based products enjoy a higher consumer acceptance and do not leave an unpleasant or sticky residue on the skin.

Training is Key

New employees should be trained on proper handwashing techniques and frequency during orientation. Show new workers where the sinks and sanitizing stations are and remind them when to wash their hands.

Employers can encourage good hand hygiene practice among all employees by providing easy-to-understand awareness materials such as posters and stickers for use in washrooms, food processing areas, and on mirrors and doors to remind employees of the importance of clean hands.

Employers can also work with their washroom services supplier to create a communications campaign to educate employees on this necessity. Free downloadable posters are readily available from established suppliers to help promote good hand hygiene practices.

A systemized approach to skin care combined with programs to educate employees about their skin allow employers to provide a simple yet cost-effective solution to help all employees adopt these proper practices. ■

Klotz is technical product manager at Deb Group. He holds extensive experience in professional skin care products to prevent work-related occupational skin diseases. Reach him at andreas.klotz@degroup.com.

Plans for an Efficient Commercial Kitchen

The most often overlooked elements when designing and expanding facilities

BY **JUDY SEBASTIAN**

An experienced restaurateur knows that both the heart and the brain of a successful restaurant rest within its commercial kitchen. Sleight of hand in a busy catering or retail operation may go a long way but engineering the chef's workstation to not only fit the theme of the food business, but to also consider best food safety practices goes much further. For someone who's considering entering the realm of hospitality by exploring either catering or retail facilities, it's best to not assume that a commercial kitchen functions just like a domestic one. When things begin to fall apart in the kitchen, it results in a domino effect that eventually snowballs into outlandish PR. Building a commercial kitchen from scratch or renovating an existing one can be done successfully with a holistic approach.

Some of the components that tend to be overlooked whilst designing and/or renovating a commercial kitchen are: approvals, risk assessments, smart space utilization, equipment selection and placement, process management, food waste management, integrated pest management (IPM), and heating, ventilation, and air conditioning (HVAC).

Approvals

Wouldn't it be a comedown to have sections of a fully purpose built kitchen torn down only because the scope of activity or the flow of work was not approved by the regulatory authorities prior to commencing the operation? It's best to be mindful of the local regulation and guidelines pertaining to the food business. There are specific food safety requirements when it comes to storage, processing, and serving certain categories of food products such as halal, certified organic, gluten-free, dairy free, etc. The rule of thumb for franchised food establishments is to not only follow the parent or corporate guidelines but also to reflect the regional food safety regulations. Working with a multi-disciplinary team that comprises members who are well versed in food flow, inventory, engineering and maintenance, fire safety, pest control, cleaning and disinfection, and waste management would not only help gain more insight but also facilitate future growth. Altering or modifying the dining area is comparatively easier than remodeling the commercial kitchen.

Risk Assessments

A good commercial kitchen is designed in parallel with the menu. Based on space availability, the kitchen needs to accommodate a linear workflow to prevent cross-contamination. For instance, modifying the menu at a later stage to incorporate a high risk product, such as homemade ice cream, presumably would result in the surfacing of various food safety deviations simply because the existing floor plan of the kitchen did not factor in requirements such as storage space, ingredient flow, and processing. Planning remains incomplete without thorough risk assessments and menu analysis.

Smart Space Utilization and Ergonomics

It's time to uncomplicate. Let's not see a commercial kitchen as mulligatawny soup.

It doesn't matter how elaborate and well-equipped a commercial kitchen is, if ergonomics was not a part of the designing process. The lesser the steps involved for members of the kitchen and service team to complete a task, the greater is the efficiency of the team. Also, through the simple principles of ergonomics, one is more likely to reduce the chances of cross-contamination, which is the ogre of any food business. Employee safety and mobility are and should be, of paramount importance. An example to illustrate ergonomics would be the use of under-counter chillers. This limits the need to walk to the allocated walk-in refrigerators frequently and also saves a lot of space. One needs to be mindful of the heights of equipment because a mismatch could not only hinder the process but also result in injuries.

Selection and Placement of Equipment

The food and beverage industry is constantly evolving and that adds to the

Creating working zones ensures seamless workflow, reduces chaos, and enhances cross-functional communication within the kitchen.

plethora of commercial kitchen grade equipment to select from. Keeping budget frames in mind, choosing the right type of equipment such as fryers, combi-ovens, under-counter refrigerators, preparation sinks, etc. depends on not just the available space, but also the workforce capacity and of course, maintenance. It's certainly a good initiative to opt for state-of-the-art equipment if the business can afford it. However, the said investment would prove to be futile if the maintenance and replacement of worn out parts proved to be a daunting task.

The main factor that the efficiency as well as safety of a kitchen relies on is the placement of the equipment. It is recommended to place fast cooking equipment, such as griddles and fryers, closer to the point of service and bulk cooking points where multiple ingredients meet, such as boiling pans and pots, within the core of the kitchen's "hot section" and distant from the service points. Not only does this cut down opportunities for cross-contamination but it also facilitates quicker assembly and delivery.

Process Management

Without having to compromise on the authenticity of a specific recipe, certain processes could be combined if not reduced to both increase the efficiency of workflow and also eliminate chances for cross-contamination. For instance, pre-sanitized vegetables could very well replace the need to sanitize the greens in-house. This technique also reduces the chances of over dosage of chlorine based sanitizer tablets used in most conventional produce washing processes. Creating working zones ensures seamless workflow, reduces chaos, and enhances cross-functional communication within the kitchen. Zones within the kitchen do not necessarily need to be visibly demarcated but they shouldn't overlap with processes that could result in cross-contamination.

Food Waste Management

The emphasis needs to lie on not just conventional waste management but reducing food wastage as well. Although time and temperature remain the pivotal elements that dictate the shelf life of food, certain variables like portions and stock rotation could ensure that food wastage remains minimal. Having good contingency plans in case a refrigerator or freezer unit breaks down would prove to be beneficial.

IPM

Ideally speaking, pest control begins as the kitchen and other areas of the premises are being constructed. Access and exit points should be sealed off from pests' entry and harborage. Choosing the right building materials would support IPM to a great extent. Electric fly killers work best when it's positioned away from sources of bright light and for obvious food safety reasons, they must never be installed atop food preparation and processing areas. Certain food businesses feel that they need to install the fly killer "somewhere." The UV lamps utilized in fly killers are designed to attract insects and installing a unit where insect activity never existed before might take a turn for the opposite. If it isn't broken, don't fix it. Baits and traps, when utilized, should be installed based on the local environment and health regulations.

HVAC

HVAC ensures a comfortable and safe work environment within the commercial kitchen. A good HVAC contractor would test for flue gases since combustion safety cannot be ignored—again, this goes back to being backed by a multi-disciplinary team during the initial phases of designing or renovating a commercial kitchen. That being said, installing a hood to extract fumes by itself does not entail a complete ventilation system. Depending on the nature of the food business, the equipment in use, and the bulk of food that is cooked, there are various regulations pertaining to kitchen ventilation systems. The general rule of thumb is vent hoods are coupled with fire suppression systems over most cooking equipment. Make-up air systems carry equal importance on the ventilation priority list and this can be competently designed provided the steam generating and heat-generating units in the kitchen are considered.

It's quite a fulfilling and satisfying experience to watch a restaurant, a café, or a retail space materialize from scratch. During the transition from "print to brick," walking the plan during buildup helps identify areas of improvement and nip away potential gaps. ■

Sebastian is a registered (GCC and U.K.) food safety consultant, speaker, and trainer with Dubai-based food safety consultancy, Apex Food Consultants. Reach her at judysebatian@gmail.com.

NEW PRODUCTS

Temperature Recorder

The DataLink 2 is used for refrigerated haulers who require independent verification of temperatures inside trucks and trailers or immediate documentation for receivers. For single-temperature or multi-temperature applications, the system uses up to three independent temperature sensors, providing an added layer of verification beyond the refrigeration system's built-in recording ability. A thermal printer lets drivers quickly produce numerical and graphical trip reports for receivers. Additionally, data can be downloaded into a personal computer for electronic logging. **Carrier Transicold, 800-227-7437, www.transicold.carrier.com.**

Ultra Soft Metal Activator

According to company, the Ultra Soft Metal Activator addresses microbial challenges on soft metal surfaces and enhances food safety in food processing environments. It has ability to penetrate and remove biofilm when combined with either Sterilex Ultra Disinfectant Cleaner Solution 1 or Sterilex Ultra CIP. It can be used for both remediation of microbial challenges as well as rotational maintenance. Product is non-acid, non-volatile, phosphate free, and compatible with wastewater systems. **Sterilex Corp., 800-511-1659, sterilex.com.**

Footwear Hygiene

Offered in six different versions, the BSX Boot Scrubber series gives food processors the ability to reduce cross-contamination from footwear. Each boot scrubber has an open, sanitary design that eliminates hidden and hard to reach areas that are difficult to clean and can harbor pathogens. Series of scrubbers gives large and small, dry and wet food processors a variety of options for cleaning footwear prior to sanitization. **Best Sanitizers, Inc., 888-225-3267, www.bestsanitizers.com.**

LC/MS/MS System

The QSight Triple Quadrupole LC/MS/MS system offers patented flow-based mass spectrometry that can enable laboratories to test highly complex samples and experience increased throughput. Combined with the company's Altus UPLC instrument, the QSight system can provide a complete solution from sample preparation to results and reporting. The system specializes in detecting a wide range of pesticides that are increasingly found in crops. It can also test foods for mycotoxins and antibiotics as well as analyze veterinary drugs and nutritional components. **PerkinElmer, Inc., 800-762-4000, www.perkinelmer.com.**

Whole Genome Sequencing Test

The Whole Genome Sequencing (WGS) test allows the food industry to identify specific pathogen strains, monitor for pathogen-related problems in the food supply, and trace outbreaks. It pairs WGS technology with company's proprietary analytics pipeline to enable retailers and manufacturers to understand how different pathogen and probiotic strains are related to one another, how they are connected evolutionarily, where they come from geographically, and with which food groups they are associated. The test is also capable of matching pathogen strains with ingredients, allowing customers to correlate the strain of bacteria with specific food ingredients and suppliers. **Clear Labs, www.ClearLabs.com.**

In Other News

Neogen receives approval from AOAC Research Institute for its AccuPoint Advanced ATP Sanitation Monitoring System.

AIB International's FDA Preparedness Inspection program helps U.S. companies, as well as those exporting to the U.S., measure their regulatory readiness before an FDA inspector arrives.

Bruker's version 3.1 Wine-Profiling module of the NMR FoodScreener platform fulfills needs for improved coverage of white wines in three most recent vintages and for better coverage of certain regions, appellations, and grape varieties.

The **LINKFRESH** 2016 ERP version for the Microsoft Dynamics AX platform includes over 50 enhancements and new features to the fresh food functionality.

MilliporeSigma's set of Steritest Symbio Pump systems accessories accelerate and streamline sterility testing workflows, such as sample handling, filtration, waste management, and transport and incubation.

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Events

JANUARY

23
FSMA Part 117: Preventive Controls for Human Food – What Managers Need to Know
Alexandria, Va.
Email ascanlin@easconsultinggroup.com or call 571-447-5500.

24 - 26
Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food
Alexandria, Va.
Email ascanlin@easconsultinggroup.com or call 571-447-5500.

25-27
FSPCA Preventive Controls for Human Food Course
Post Falls, Idaho
Email paulap@uidaho.edu or call 208-364-6188.

31-2
IPPE
Atlanta, Ga.
Visit http://ippexpo.com/.

FEBRUARY

14-16
Practical Food Safety & HACCP Workshop
Boise, Idaho
Email paulap@uidaho.edu or call 208-364-6188.

26-1
Refrigerated Foods Association's 37th Annual Conference & Exhibition
Amelia Island, Fla.
Visit http://www.refrigeratedfoods.org/rfa-conference or call 678-426-8175.

27-2
Global Food Safety Conference
Houston
Visit http://www.tcgffoodsafety.com/.

MARCH

5-9
Pittcon
Chicago
Visit http://pittcon.org/pittcon-2017/.

7
FSMA Part 117: Preventive Controls for Human Food – What Line Staff Need to Know
Charlotte, N.C.
Email ascanlin@easconsultinggroup.com or call 571-447-5500.

8-10
Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food
Charlotte, N.C.
Email ascanlin@easconsultinggroup.com or call 571-447-5500.

9-11
Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food
Chicago
Email ascanlin@easconsultinggroup.com or call 571-447-5500.

MAY

8
FSMA Part 117: Preventive Controls for Human Food – Dietary Supplements
Chicago
Email ascanlin@easconsultinggroup.com or call 571-447-5500.

8-11
Food Safety Summit
Rosemont, Ill.
Visit http://www.foodsafetysummit.com/.

23-25
Food Microbiology Short Course
University Park, Penn.
Visit http://agsci.psu.edu/foodmicro or call 877-778-2937.

JUNE

13-15
United Fresh
Chicago
Visit http://www.unitedfreshshow.org/.

20-22
The 51st Annual Microwave Power Symposium
Miami
Visit http://impi.org/symposium-short-courses/.

SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to December/January 2017 issue at www.FoodQualityandSafety.com or type the article headline in search box.

ARTICLE: Texture and Color Analysis of Lentils and Rice for Instant Meal Using Image Processing Techniques

Typical approaches for measuring color and texture properties are mostly time-consuming. This article discusses how an image-based method was used to evaluate texture and color in lentils and rice subjected to freeze-drying for an instant meal. Cooked and cooked freeze-dried rehydrated lentils and rice were analyzed by scanning electron microscopy. Texture properties were analyzed by texture analyzer and image analysis. Color was performed with a digital camera. Results for lentils showed that image features such as contrast, correlation, energy, and homogeneity calculated from Gray-level co-occurrence matrix had high correlations with mechanical features of hardness, adhesiveness, chewiness, and gumminess. **Journal of Food Processing and Preservation, Volume 40, Issue 5, Pages 969–978, October 2016.**

ARTICLE: Natural Antimicrobial Edible Coatings for Microbial Safety and Food Quality Enhancement

Natural antimicrobial agents have been investigated as alternatives to synthetic ones for ensuring food safety and quality. However, the practical use of these preservatives in the food industry is limited due to their negative impact on the odor and taste of food products, as well as the early loss of functionality due to their rapid diffusion and interaction with food components. This review highlights the potential use of polymeric edible coatings for the incorporation of natural antimicrobial agents and the improvement of their controlled release in food systems. The most recent findings regarding the application of nano-encapsulating and multilayered/nano-laminate delivery systems in food products are also discussed. Comprehensive Reviews in Food Science and Food Safety, Volume 15, Issue 6, Pages 1080–1103, November 2016.

ARTICLE: *Bacillus* Spores in the Food Industry

Bacterial spores are of concern to the food industry due to their ability to survive processing, the various steps designed to kill the vegetative cells, and their potential to subsequently germinate and grow in food. This article outines the importance and challenges presented by *Bacillus* spores, with a focus on *Bacillus cereus*. The article describes the structure and the mechanism of resistance of these spores, and the steps involved in their germination. Novel technologies, using no or only mild heat treatments, to inactivate *Bacillus* spores are covered, including UV radiation, pulsed electric field, and high-pressure processing, both as stand-alone techniques or techniques as part of a hurdle approach. Comprehensive Reviews in Food Science and Food Safety, Volume 15, Issue 6, Pages 1139–1148, November 2016.

ARTICLE: Rheological Characteristics and Microstructure of Milk Yogurt as Influenced by Quinoa Flour Addition

This review explores the effect of quinoa flour addition on the physicochemical and rheological properties and microstructure of yogurt. Adding quinoa flour led to an

increase of milk acidity with a reduction of the pH value leading to milk gelation. Rheological studies showed that all yogurt samples have a shear thinning behavior, described by the power-law model. Up to 1% quinoa flour addition flow behavior index decreased, while the consistency coefficient and apparent viscosity increased significantly. The epifluorescence light microscopy images of yogurt samples showed that the gel network presented the same stability with lower resistance to syneresis at a high level of quinoa flour addition. Journal of Food Quality, Volume 39, Issue 5, Pages 559–566, October 2016.

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Deborah McKenzie

Deborah McKenzie, Senior Director
Signature for AOAC Research Institute

September 09, 2016
Date

NSF tested and compared the AccuPoint system to the competitors, and AOAC certified the performance of the system. With these references we feel we have the best overall ATP Sanitation Verification available, and we believe once you put it to the test you will too.

Learn more by viewing the video (YouTube - "A Comparison of ATP Sanitation Verification Systems") or by visiting our website.

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