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DECEMBER/JANUARY 2016

Food Quality & Safety

FARM TO FORK SAFETY

Industry needs to prepare as FSMA rules take shape

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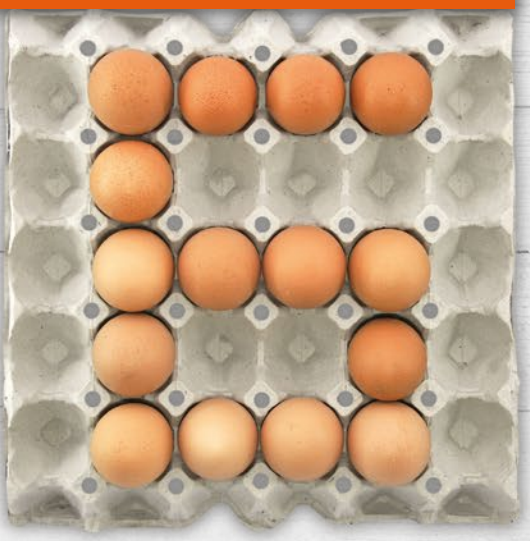

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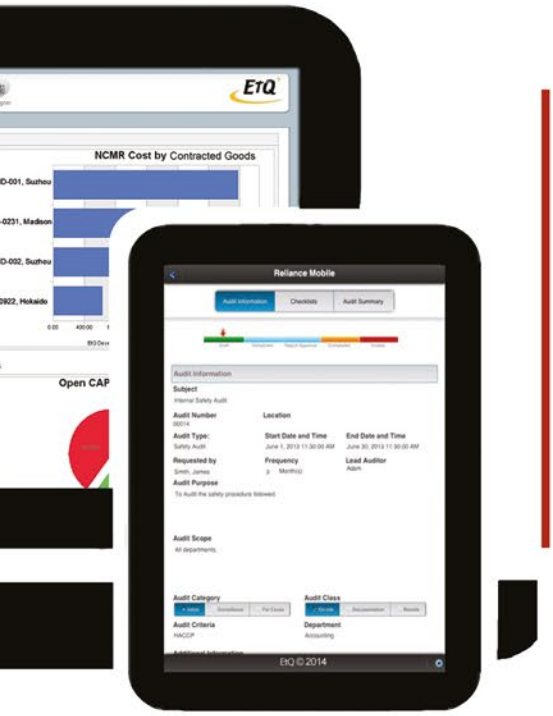

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BY LINDA L. LEAKE, MS

Safety & Sanitation

An introduction to understanding the differences between sanitizing and disinfecting, and how to select and use the proper sanitizer

BY DALE A. GRINSTEAD, PHD

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From The Editor

"Transparency" has been the buzzword the last few months of 2015. More food companies are implementing transparent initiatives in response to lack of consumer trust, as evident in recent industry studies.

For example, Trace One's "Global Consumer Food Safety and Quality" survey of over 3,000 shoppers across nine countries found that only 12% of consumers wholeheartedly trust the safety of the private and national food brands and only 10% trust the quality. Furthermore, 27% of consumers do not even trust the information printed on the product labels.

The majority of respondents (91%) also said it's important to them to know where their food comes from, but 62% said they're not provided with enough information about what's in their food and its origins.

"Consumers are demanding more information and want reassurances that the foods they're eating are safe—and originating from reliable sources," says Chris Morrison, CMO, Trace One. "Brands that go above and beyond to share accurate and reliable product information with consumers will ultimately be rewarded with increased consumer trust."

The Center for Food Integrity (CFI) also released its latest research, "A Clear View of Transparency and How it Builds Consumer Trust," which proved that increasing transparency in farming, food production, and processing will increase consumer trust.

The online survey of 2,000 people revealed the practices that consumers ranked as important in demonstrating transparency, which include providing information on product labels, offering engagement opportunities through company websites, and making results of third-party audits publicly available.

And when asked to choose between food companies, farmers, grocery stores, or restaurants, which did respondents hold most responsible for transparency? Food companies.

"This study clearly shows consumers hold food companies most responsible for demonstrating transparency..." says Charlie Arnot, CEO, CFI. "Even when it comes to on-farm animal care, an area one might assume people look to farmers to provide, consumers told us food companies are most responsible. This could lead to food companies requiring more information from their suppliers and reporting more information to consumers when it comes to the treatment of animals raised for food."

Transparency of food ingredients, origins, and production processes is no longer optional. If you haven't yet implemented transparent initiatives, perhaps it's time to make this your New Year's resolution.

Marian Zboraj
Editor

Food Quality & Safety
FARM TO FORK SAFETY

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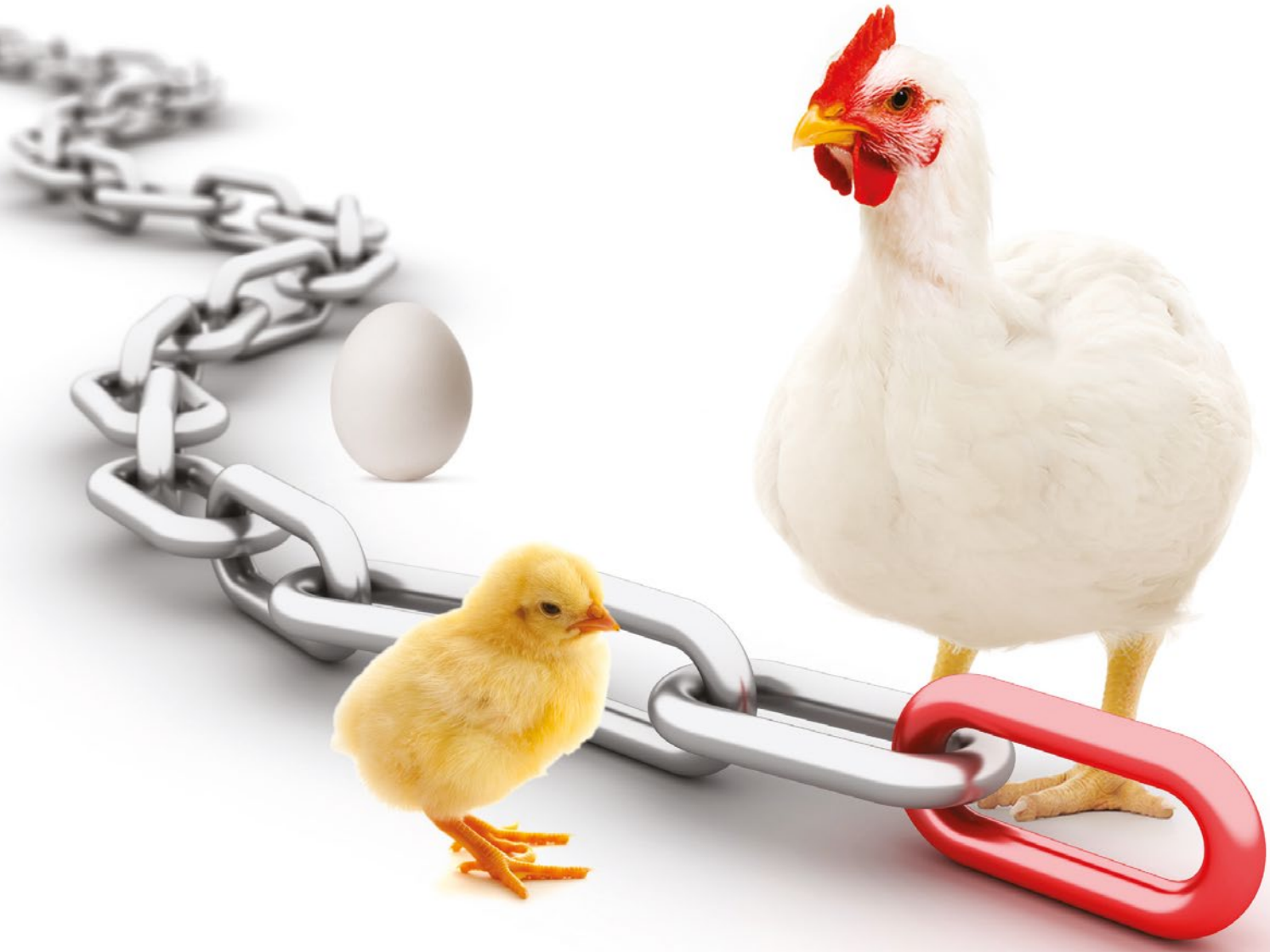

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NEWS & NOTES

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FDA Approves Genetically Modified Salmon

As reported by Reuters, federal regulators cleared the way in November for a genetically engineered salmon to be farmed for human consumption in the first-ever such approval for an animal whose DNA has been scientifically modified. The U.S. FDA's approval of the salmon, developed by AquaBounty Technologies to grow faster than conventional, farmed salmon, followed years of deliberations. It is now declared that the salmon is as nutritious as normally grown Atlantic salmon, which means the salmon will not require special labeling. Several genetics experts voiced support for the FDA's action, but some groups opposed to genetically modified foods voiced concern. The approval for the fish, to be sold under the AquAdvantage brand, comes with the condition that the salmon be raised only in two specific land-based, contained hatchery tanks in Canada and Panama, and not in the U.S.

Tips for Reducing Food Waste

The Food Waste Reduction Alliance's (FWRA) updated guide provides practical steps and examples to help food manufacturers, food retailers, and restaurants cut food waste. The second annual "Best Practices and Emerging Solutions" guide highlights ways that companies can begin or expand their food donation or food waste diversion programs. Compiled by FWRA, a cross-sector industry initiative led by the Food Marketing Institute, the Grocery Manufacturers Association, and the National Restaurant Association, the guide focuses on strategies to keep food out of landfills, and to reduce food waste at the source. The guide contains case studies, model practices, and emerging solutions.

New Resource on Sampling

In November, the U.S. FDA announced a new web resource to share more information about its sampling programs for food safety and posted new information on a more robust surveillance sampling approach under development. In addition, the agency plans to sample and test cucumbers and hot peppers under this program in fiscal year 2016. The FDA will publish information regarding test results on the web, including total number of samples collected/tested, and collection date, sample type, and pathogen detected for positive samples. The agency began developing a new surveillance sampling approach in 2014. During the first year, the FDA focused on sprouts, whole fresh avocados, and raw milk cheese. The FDA will release data on the recently completed surveillance sampling in the near future.

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OSU to Lead Food Safety Center to Help Farmers, Processors

Oregon State University (OSU) will administer a new $1.2 million center that aims to help small- and mid-sized farms and food processors in 13 western states prevent foodborne illnesses. The initiative was announced by the federal government as part of an effort to help growers and processors of fruits, vegetables, and nuts comply with requirements established under FSMA. The center, which is not an actual building, is one of four new regional hubs across the country. OSU and its partners will use the funding—a third of which will go to OSU—to develop trainers to teach others how to conduct workshops for small- and mid-sized farms, beginning farmers, small-scale food processors, and wholesale produce vendors. OSU and its partners will work with The Produce Safety Alliance and Food Safety Preventive Control Alliance to develop trainers.

Guide Helps Food Processors Better Control Allergens

The U.S. FSIS releases new guidelines to assist meat, poultry, and processed egg product producers in properly managing ingredients that could trigger adverse reactions among consumers with allergies or other sensitivities. Over the last several years, in part due to new actions by FSIS, there has been an increase in recalls of FSIS-regulated products due to undeclared allergens. These problems are often caught by FSIS inspectors during labeling checks and are the result of changes to ingredient suppliers, products being placed in the wrong package, or changes to product or ingredient formulations. By following these new guidelines, establishments can better ensure that product labels declare all ingredients, as required by law, and that products do not contain undeclared allergens or ingredients.

Business Briefs

NSF International achieves Independent Laboratory status as recognized by the AOAC RI, qualifying its labs to test and evaluate test kits and methods submitted to AOAC PTM program.

Mérieux NutriSciences' Sensory and Consumer Research Center, Bentonville, Ark., gains ISO 17025 accreditation. In addition, **Mérieux** and **Danone** enter into a worldwide food safety partnership covering strategic fields for both companies.

Shimadzu Scientific Instruments opens a new 2,000-sq.-ft. Shimadzu Laboratory for Advanced Applied and Analytical Chemistry at the University of Wisconsin-Milwaukee for campus research and for use as a classroom for teaching the theory and practice of mass spectrometry.

Agilent Technologies Inc. signs a formal agreement with **Thermo Fisher Scientific** to exchange instrument controls to improve productivity using software and instruments from both companies.

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Washington Report

China Buckles Down on its Food Companies

Stricter regulations on domestic food producers and distributors will also impact the U.S. and other countries that export products to China

BY **TED AGRES**

Over the past two decades, China has been plagued by scores of food scandals, ranging from the lethal (intentional adulteration of infant milk formula) to the bizarre (exploding watermelons and glow-in-the-dark pork). Now, with more than 70 percent of its population expressing serious concerns about the safety of the food supply, authorities in China have become more serious about improving the situation, both on paper as well as in practice. These changes will affect U.S. and other companies that export products to China.

In April 2015, Chinese lawmakers published tough new amendments to the nation's Food Safety Law, which went into effect on Oct. 1, 2015. The amendments impose "the heaviest civil, administrative, and criminal penalties yet for offenders and their supervisors," the official Xinhua News Agency reported. In addition to heavy civil and criminal punishments, company officials found guilty of violating the law face restrictions on "loans, taxation, bidding, and land use." Large rewards will be offered to consumer and industry whistleblowers; trials of selected "notorious" food crimes will be broadcast live; and provincial police departments are establishing food safety units to specialize in combatting food crime.

While the amendments focus on domestic Chinese food producers and distributors, they will also impact companies in the U.S. and elsewhere that export food or food products to China. For example, at least once every three years, Chinese food importers must conduct onsite audits of facilities outside of China that export meat products, health foods, and infant formula. The inspections may be conducted by accredited third-party auditors. The amendments also address import inspections at ports of entry by risk levels and food labeling and claims.

The amendments are broadly worded and build on the nation's existing food safety framework. Since April, government agencies have been issuing regulations and national food safety standards to implement the new amendments, and interested stakeholders had been invited to comment. The process is ongoing.

While China is notorious for enacting laws and regulations that are largely ignored or only selectively enforced, this time things may be different. "With passage of the new rules, we should assume the Chinese are taking enforcement more seriously than they used to," says David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. "But enforcement in China is also jurisdictionally dependent and very much driven by local politics in terms of who gets whacked for what," Dr. Acheson tells *Food Quality & Safety* magazine. "The message for U.S. companies is to be very careful."

Overhauling the Food Safety Framework

In 2008, domestically produced infant milk formula was found to have been laced with the toxic industrial chemical melamine in order to spike its apparent protein content. At least six infants died and about 290,000 suffered kidney damage and other injuries. At least 11 countries stopped importing Chinese dairy products. In response, the Chinese government ordered criminal prosecutions, which resulted in executions and lengthy jail terms for company executives as well as the sacking of several government officials.

Also in response, the Chinese government in 2009 overhauled the nation's food safety legal framework and enacted a new Food Safety Law. Under the law, responsibilities for enforcement and oversight were relegated to an alphabet-soup combination of agencies, resulting in overlapping authorities and even conflicting standards. Under the 2009 law, for example, the National Health and Family Planning Commission (NHFPC) was the primary regulator, while responsibility for food production fell to the General Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ). Food distribution, on the other hand, came under the State Administration of Industry and Commerce, while catering services were

overseen by the China Food and Drug Administration (CFDA). Making matters more complicated, food recall standards established by AQSIQ differed from those that had been established by the Food Safety Law, in effect at the same time.

"This regulatory system resulted in inconsistent law enforcement standards which were taken advantage of by unscrupulous merchants," wrote Liza Mark, a partner in the Haynes and Boone law firm's Shanghai office, on the company's website. Food safety incidents continued to occur with regularity, including a well-publicized "gutter oil" scandal and widespread counterfeiting and intentional adulteration of food with often toxic chemicals. As recently as this past June, for example, authorities seized 800 tons of frozen smuggled meat, some of it more than 40 years old. "It was smelly, and I nearly threw up when I opened the door," said Zhang Tao, an administration official, as reported in China Daily.

These and other food safety incidents "highlighted the defects deeply rooted in the multiple and uncoordinated regulatory systems of the 2009 Food Safety Law," reported Mark. The new amendments attempt to redress this by shifting primary authority and responsibility for food safety to the CFDA, with many inspection and compliance responsibilities pushed down to the provincial and local levels. CFDA will be the primary regulator; NHFPC will monitor and assess food safety risks and develop national standards; and AQSIQ will regulate imports and exports. "Although it will take some time, stakeholders can expect that the contradicting regulations previously issued by different regulators under the 2009 Food Safety Law will be methodically eliminated," Mark predicts.

New Regulations

Over the past several months CFDA has issued new regulations for ordering food recalls. It has also proposed combining food distribution licenses with restaurant service licenses, for pre-approval of infant formula and "medical food" supplements, and for post-approval supervision of food manufacturers and food distributors. China's AQSIQ has released regulations to guide local ports of entry on import inspections, including establishing an inspection categorization system by risk assessment and risk level. Legal obligations will fall on both domestic importers as well outside exporters. The measures also detail the conditions necessary for imposing and lifting temporary bans on food imports.

In keeping with China's increasingly wired business sector, new measures are intended to regulate online food trading activities, including food distribution within the national borders. "Whenever an online trading platform discovers unsafe food, it is under an obligation to immediately cease the distribution and recall affected products based on a negative investigation result," explains a whitepaper prepared by the Keller and Heckman LLP law firm. For the first time, food wholesalers are also required to create and maintain recordkeeping systems to capture detailed information including food name, specifications, production dates, sale quantity, shelf life, and buyers' name and contact information. The records must be maintained for at least two years.

As mentioned, many inspection responsibilities are pushed down to provincial and local levels. Shanghai, for instance, has introduced rules requiring industry to be responsible for tracing safety information related to all food and edible agriculture products produced, distributed, and served by restaurant service providers within its administrative region. At the national level, food additive merchants must check suppliers' permits and quality certificates and maintain detailed transaction records. CFDA will play a major role in coordinating provincial and local inspection activities while the companies themselves will be increasingly responsible for self-inspection and reporting results to local authorities.

When it comes to exporting to China, companies that are compliant with U.S. food requirements should generally meet Chinese requirements, says Craig W. Henry, PhD, vice president for global business development, Americas, Decernis LLC. "I would assume that U.S., Canadian, and European products should meet or even exceed China's food safety requirements," Dr. Henry says. "But now when you get into labeling, claims, and things like that, it gets to be more complicated and looked at case by case," he tells *Food Quality & Safety* magazine.

Fearing Their Food

Chinese citizens have grown increasingly worried about the safety of their food. The percentage of those expressing serious concerns about food safety has nearly tripled since the country's melamine scandal in 2008. According to a Pew Research Center survey conducted in China in April and May 2015, 71 percent of adults say food safety is a serious problem, with 32 percent calling it a "very big" problem—up 20 percentage points from 12 percent in 2008. Fewer than half (43 percent) think the situation will improve over the next five years, with 27 percent believing it will get worse, and 22 percent expecting it to remain unchanged.

"There is massive opportunity for U.S. companies in China, but it is also a very tough road to navigate. If you take one misstep—or even a perceived misstep—you will get whacked," Dr. Acheson says. He cites as an example OSI Group LLC, a private U.S. meat processor whose Shanghai Husi Chinese operations were shut down in 2014 over allegations of having sold out-of-date meat to McDonald's and KFC outlets throughout the country. In September 2015, Chinese prosecutors also brought criminal charges against 10 people connected with two OSI meat-processing facilities, including a plant manager. "There's lots of opportunity in China, but you need to tread cautiously," Dr. Acheson advises.

China is also becoming a focal point for new international food safety initiatives. In September 2015, Mars Inc., opened its Global Food Safety Center, a $15-million research and training facility located in Huairou, just north of Beijing. The facility will employ 30 Mars scientists and provide fellowships for other academic and regulatory researchers to conduct precompetitive food safety research. The facility will house analytical chemistry and microbiology labs as well as interactive training labs. Mars says 95 percent of the research results will be placed in the public domain. "We firmly believe that in order to ensure generations of families have access to safe and nutritious foods, we must work together to evolve food safety management programs and create robust, sustainable supply chains," said David Crean, corporate R&D vice president at Mars, in a statement. ■

Agres is a freelance writer based in Laurel, Md. Reach him at tedagres@yahoo.com.

FSMA Update

Forensic Analysis

FSMA mandates more stringent measures to identify food product contaminants and their sources

BY **CRAIG S. SCHWANDT, PHD**

A microscopist performs particle isolation in one of McCrone Associates' ISO Class 5 cleanrooms.

Recently, the FDA established several of the Food Safety Modernization Act's (FSMA) final rules for compliance. These include preventive controls for human food and animal feed, produce safety, Foreign Supplier Verification Program (FSVP), and third-party accreditation and certification. Compliance with the regulations is required within 18 months to two and a half years depending on the specific regulation. But what do FDA auditors really expect to see when they visit your business?

The FDA's primary concern is ensuring that companies are following the regulations and therefore sends auditors to inspect the compliance records that companies keep. Records demonstrate that the requisite steps were taken to meet compliance with the regulations. With regard to identification of contaminants, some manufacturers may have to significantly augment their practices. Specifically, greater use of forensic or investigational analysis will be required. For example, food companies that obtain any portion of their product from outside of the U.S., whether whole or ingredients, will be subject to FSVP regulations that require companies to investigate the origin of contaminants that may occur in their product. Under FSVP, the FDA will want to see records for all stages of testing, including origin of contaminants. Although bulk analyses are great at establishing the presence of contaminants, bulk methods are not particularly good at identifying the what, when, and where of contamination; answering these questions typically requires forensic or investigational analysis methods.

A New Paradigm

In the past, investigational analysis was not usually necessary in the food industry; the accepted norm was that most food ingredients were generally recognized as safe (GRAS). Establishing the provenance of contaminants can be costly, so firms typically limited investigational or forensic analysis to special cases, such as spices, where the product consists of a single, relatively high-priced ingredient, making the cost of analysis worthwhile. Alternatively, for some foods like spices, it was cheaper for large companies to simply buy or deal with source suppliers directly, removing middlemen and any incentive for economically motivated adulteration. However, the entire product processing path presents opportunities for contamination; both intentional and unintentional.

Enactment of FSMA and especially the FSVP now requires the food industry to provide more assurance and ultimately conduct more testing. The objective is no longer to simply identify contaminants but to understand and document how they ended up in the product. Records also need to indicate who conducted the work during all stages of the identification.

To minimize the possibility of bias, the investigational analyses are best conducted, or corroborated, by an independent laboratory. The pharmaceutical industry has been subject to these types of regulations for years. This paradigm, although new to the food industry, brings positive advantages. For example, investigational analysis can provide greater confidence for establishing that a GRAS ingredient is safe even though a contaminant might be present. A food processor can remove certain contaminants, or prevent further contamination, once it understands how the contaminants manifest themselves in the product. Investigative analysis provides the pieces to the forensic contamination puzzle.

Multiple Microscopy Methods

Any instance of product contamination or product failure can be traced to discreet particles or residues that may not be clearly visible to the naked eye. The size of contaminant particles can range from millimeters down to nanometers. Bulk analytical methods may identify the presence of a contaminant at trace or ultra trace concentrations, however they may not be of much use in identifying how that element came to be part of the product. Isolating the contaminants from the host product, on the other hand, allows for successful identification of the contaminants.

Isolating contaminant particulate begins with the use of an optical stereo zoom microscope. Visual inspection of an adulterated sample, in comparison to a reference sample, usually reveals a great deal about the contaminant, especially if it is particulate in nature. For example, metal contamination may occur as large pieces easily visible to the unaided eye, or as gray, brown, or orange (and sometimes green) spots in the product. Contaminant material can be isolated from the product under magnification using custom tools for handling microscopic size samples. A microscopic subsample can then be mounted on a suitable substrate for further

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analyses and identification. Continuing with the metal particulate example, inspection of the discolored samples with scanning electron microscopy (SEM) and X-ray microanalysis using an energy or wavelength dispersive spectrometer system (EDS or WDS), may reveal that the discolored areas contain micrometer sized particles of metal, even gauging the extent to which they have oxidized. X-ray microanalysis can establish the alloy type, allowing the manufacturer to narrow the search based on the product's exposure to machinery composed of different alloys. This method of isolation and analysis is so powerful that sometimes the source of contamination can be traced to non-standard replacement parts installed by unqualified repair technicians.

In instances where polymers or other organic compounds are the contaminants, isolating these particles and pressing them out onto potassium bromide crystals for microscopy-based infrared spectroscopy yields amazing identification success.

When additional information is required, other methods provide a wide range of information about the nature of the particulate. These methods include micro X-ray diffraction, Raman microspectroscopy, transmission electron microscopy, electron spectroscopy for chemical analysis, and some mass spectrometry methods geared toward surface analysis.

Once particulate contaminants are isolated and fully characterized with multiple microscopy-based methods, it is generally easier to deduce how the contaminants came to be in the sample. This knowledge allows the product producer to correct the contamination issue at its source.

Collaborating with a Forensic Laboratory

Manufacturers and producers have a couple options when it comes to addressing their FSMA contamination identification requirements. The first is to construct an in-house laboratory capable of meeting the requirements in terms of competency, training, and accreditation. The second is to utilize the services of third-party labs that are already accredited and ready to meet the quality requirements necessary for successful scrutiny by the FDA. Although many U.S. contract labs advertise compliance to current Good Manufacturing Practices (cGMP), a growing number of companies are operating at a global level and, therefore, need facilities that meet global standards. As such, meeting ISO standards is becoming a widely accepted and recognized quality program. ISO/IEC 17025:2005 covers the general requirements for the competence of testing and calibration laboratories, which includes elements beyond cGMP requirements. For ISO accreditation, a lab develops its quality program and then becomes accredited after inspection and approval by an ISO-recognized inspection company. With this system, manufacturers and producers can easily select an accredited lab to conduct their contaminant analysis and rest assured that the samples were analyzed using methods meeting the globally recognized ISO quality standard.

While many contaminants are particulate-scale materials that are easily identified and their origin established with multiple microscopy methods, using an ISO 17025 accredited lab can simplify meeting FSMA requirements when contamination is an issue. ■

Dr. Schwandt is a senior research scientist and director of industrial services at McCrone Associates, Inc., and co-teaches several courses at Hooke College of Applied Sciences, LLC, Westmont, Ill. Reach him at cschwandt@mccrone.com.

Industry Insights

Paths of Food: Challenges Shaping the Future of Industry

The "big picture" in the future of food is defined by technology, what it makes possible, and the new challenges it brings to the forefront | BY **LISA TRYSON**

Globalization, safety, regulation, efficiency, and refrigerants are now leading variables in the complex food-delivery equation. What the food delivery system will be in a decade will depend largely on industry creativity. Innovation across a wide range agenda will be required. It's important to first look at the full range of forces driving industry change and how they interact.

People and Production

In 1910, the U.S. population was about 92 million people, according to the U.S. Census Bureau, of which about 46 percent lived in cities. A century later, in 2010, the population had exploded to more than 300 million people, approximately 80 percent of which lived in cities. In three generations, the U.S. transitioned from largely rural to overwhelmingly urban, while more than tripling its population. These trends continue today.

Simultaneously, agricultural production experienced a revolution. In 1870, 70 to 80 percent of America's population worked in agriculture. According to USDA estimates, a mere 2 to 3 percent of the population provided the national food supply in 2008—made possible by advanced industrial technology and modernized management.

The fundamentals are shifting not only in the U.S. It is estimated that the global population will increase by two billion in the next 25 years, a number that cannot be fed unless advanced agriculture becomes a global tool. But if it does, the quality of life around the world will be transformed.

The picture that emerges is of a new kind of global society and a new kind of global agriculture making possible a quantum leap in the conditions of lives everywhere. But these changes can be viewed from other angles. For example, food prices in the U.S. have increased 35 percent since 2009 and 48 million people in the U.S. become sick each year because of foodborne illness. Shifts in U.S. population growth and urbanization, plus the development of technology, more sophisticated supply chains, and the broad need to do more with less, have transformed American food delivery. And growing reliance in the U.S. on globally sourced food will fuel a similar movement beyond American borders. It will also provide both added price pressures and greater support for embracing safety and efficiency as central themes of all future strategic thinking on food worldwide.

Globalization

Retailers now reach around the world to optimize costs, as well as for wider varieties and substitutes for foods scarce on local shores. But globalization has large implications for food safety, not least because exporting countries vary in safety standards. For example, global food supply chains now dominate the seafood marketplace for Americans. According to the National Oceanic and Atmospheric Administration, 91 percent of the seafood consumed in the U.S. is imported. But a 2011 study by Johns Hopkins Center for a Livable Future notes that only 2 percent

of imported seafood is tested for contamination. So, while profit margin pressures have driven the globalization of the food chain, globalization has also imported a vast breach in the U.S. food safety regime, which carries risks for brands and of financial liability.

The Demand for Safety

Food safety has long been a keystone in food-delivery strategy. But improvements in food delivery have created new vulnerabilities in safety, even as earlier risks are better addressed. Changes in warehousing strategy, for example, mean refrigeration needs change as well—both within buildings and during transportation. More processed food means less spoilage of whole foods but also more and varying points of contamination risk—during processing and in moving from the processing plant to the grocery store.

More fundamental safety challenges, however, may now arise from technology. Technology makes modern food possible. It also gives rise to a delivery chain that is steadily more complex, agile, dynamic, and multi-dimensional. Each link in the chain involves discreet and quickly evolving possibilities and needs—in the field (whether domestic or overseas), perhaps at more than one location, in multiple transportation avenues, and in new storage and display facilities. The safety challenges resulting from such changes in food delivery are essentially the result of the broad trend toward faster, deeper technological innovation. They will be as complex and ever changing as the technologies that create them.

The Food Safety Modernization Act, or FSMA, of 2011 was designed to address not only domestic food safety issues but also the quality concerns associated with the globalization of food made possible by technology. It was the biggest change in American food safety regulation since the FDA was created, and it effectively shifted key responsibilities for ensuring the integrity of food from the FDA to the private sector. In lieu of inspections and enforcement, the Act relied heavily on setting outcome standards and leaving it to the private sector to decide how the outcome would be achieved.

The Occupational Safety & Health Administration (OSHA) regulates the safe use of refrigeration systems, such as those that use ammonia. Despite its Process Safety Management (PSM) program, which has been in place for over 20 years, safety incidents involving high-charge ammonia refrigeration systems still exist. While resources to address facility safety have expanded, a tension has developed between the culture of past practice with growing economic pressure on one hand and PSM priorities on the other. To comply with PSM appropriately, the industry needs to change the basic design of facilities and systems and retrain its workforce.

The Need for Efficiency

Logistics and processing are vital to achieve efficiency in food distribution. One of the most defining revolutions in American industry has been the shift to just-in-time delivery systems, and "just-

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in-time" is now reshaping the world of food. Grocery chains are re-crafting their warehouse strategy, reducing inventories, streamlining transport processes, and cutting costs.

Simultaneously, there has also been greater emphasis on near-the-field processing, chilling, and freezing, which have further mandated changes in food transport, refrigeration, and energy.

While vast improvements in efficiency have been achieved, and the evolution of logistics and processing is likely to be a major part of the future of food, forward-looking refrigeration product innovations could harbor the potential to yield even greater unexpected efficiencies—and business opportunities. But the evolution of efficiency is not without challenges.

The portion of America's food supply that is processed before it reaches the grocery store has grown geometrically over the last decade. The shift was initially driven by consumer demand for greater convenience, but, more recently, the shift is also being driven by logistics and cost—which pay back to both price-conscious consumers and ROI-conscious investors. So, while food may now see fewer steps in segments of the distribution chain, there will be for some foods more steps in the early stages of the chain, as more food is moved through processing procedures instead of arriving at the grocery store in whole form. And since many of the new processing steps represent new points of vulnerability in food safety—i.e., storage, handling, and potential exposure—the quest for efficiency and the quest for safety are in tension with one another.

Compromised safety can mean wasted food and perhaps a crippling hit to a brand, both of which will minimize the benefits sought through efficiency. Compromised efficiency can weaken sales in the face of price competition and undercut returns to investors. The tension between safety and efficiency, then, is an inescapable systemic challenge facing food delivery for the foreseeable future—and, as if more were needed, the challenge has recently taken on even further complexity.

There is now an emerging demand for fresher foods, which has meant that whole foods are moving from field to store faster. The quest for freshness adds new time pressures to the food chain. Typically, the task is to provide a safety-ensuring chill early and consistently through the increasingly rapid transportation process. Yet, the matter is not always straightforward, since some pathogens, now more numerous and globalized than ever, have been discovered to flourish in cold temperatures.

> The picture that emerges is of a new kind of global society and a new kind of global agriculture making possible a quantum leap in the conditions of lives everywhere.

The relationship between safety and efficiency is not getting simpler, and the need is growing for a new approach to both: better integration of refrigeration strategy and equipment design, with systematic input from the science of food safety.

Energy and Refrigerants

In 2010, the USDA reported that 15.7 percent of the nation's energy consumption in 2007 went into food systems, up from 14.4 percent in 2002. Globally, according to the Food and Agriculture Organization of the United Nations, agrifood accounts for 30 percent of world energy consumption—70 percent of which is consumed beyond the farm. As the developing world industrializes, the percentage of total used energy absorbed by food delivery will shrink. But the clear message is that food delivery is a massive consumer of energy, and that consumption grows and keeps growing nominally as an economy becomes more mature.

In the U.S., according to the USDA, food's rising energy use accounts for a whopping 80 percent of America's total increase in energy consumption over recent years. If that is not enough to command attention, consider this: world agrifood energy accounts for 20 percent of the world's greenhouse gas emissions. Moreover, the third of world food that is wasted accounts for 38 percent of the energy consumed by world agrifood.

The energy challenges confronting the food chain inevitably draw attention to issues of refrigeration and refrigerants. Refrigeration is a core function within the food chain, and refrigerants are its lifeblood. But the primary elements of the refrigerant regime are in flux, with consequences for both refrigeration and energy.

According to a recent study, the average household has a climate impact related to food of about 8.1 tons of carbon dioxide per year, a significant portion of which is related to the energy used in refrigeration. The U.S. has increased efforts to phase down the use of hydrofluorocarbons and is moving toward low global warming potential (GWP) solutions. In the alchemy of refrigerants, this action in turn brings to the forefront the issue of whether refrigerant charges can be reduced.

Low-GWP solutions include both non-carbon and high-efficiency options. Both cut the global warming impact of refrigeration, as do efforts at leak mitigation. So while timetables are uncertain and final decisions on applications are challenging, companies operating as part of the food chain will soon be moving onto the "fresh ice" of new refrigeration technologies driven in part by efforts to cut electrical power consumption.

Conclusion

From population growth to global economic development and shifts in urbanization, a transformation of food fundamentals has already begun. Globalization of the food chain has redefined the industry's safety risk profile. Rising demands for efficiency reshape the safety challenge. And all of that is occurring while refrigerants and refrigeration are being rethought from the ground up because of concerns over energy and climate.

The world of food is now confronting fast moving pressures that have washed through many industries, and none of those industries have looked the same a decade later. Food will be no exception. Perhaps the most urgent task for the executives who lead the food industry is not that of meeting the specific challenges, but of redefining their basic orientation to accommodate change that is constant, scope that is global, and safety, efficiency, and technological demands that will require a new caliber of management. ■

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blog

ARE YOU READY?

Industry needs to prepare as FSMA rules begin taking shape in 2016

BY **TED AGRES**

The food industry and government regulators alike will face significant challenges in meeting requirements of the Food Safety Modernization Act (FSMA), which begin taking effect in 2016. In 2015, the FDA published final regulations for five of the seven major FSMA rules, establishing deadlines for food companies to embrace new manufacturing processes and requirements for testing, monitoring, recordkeeping, and reporting—all designed to ensure that safety is built into every link of the food chain, from raw materials, to transportation, to storage.

"Most companies want to do the right thing; many are doing it now," said Michael R. Taylor, FDA deputy commissioner for foods and veterinary medicine, in his blog following the multistate outbreak of *Listeria monocytogenes* tied to Blue Bell Creameries ice cream in early 2015. "Ultimately, the only way we will achieve the goals that we are focused on—the goals that consumers expect us to achieve and that industry wants us to reach—is if we have a system in which industry is systematically, every day, putting in place the measures that we know are effective in preventing contamination."

Missing court-imposed deadlines by several days, the FDA in 2015 published long-awaited final regulations for the preventive controls for human food, preventive controls for animal food, the produce safety rule, the Foreign Supplier Verification Program, and third-party certification of auditors for foreign suppliers. FDA must publish final rules for the sanitary transportation of food and for countering intentional adulteration in the first half of 2016.

"Will food companies understand what they need to do to be in compliance with all these rules, and will FDA inspectors be properly trained on how to enforce them?" asks David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. "I am hearing these questions a lot. For FDA, doing so will require money and resources, and we know the agency doesn't have what's needed," he tells *Food Quality & Safety* magazine.

Plans for Preventive Controls

Things will not be easy for industry, either. The first FSMA deadline comes September 2016, when large companies (having 500 or more full-time equivalent employees) must comply with the preventive controls rules for human food. Small companies (fewer than 500 employees) will have until September 2017, and very small businesses (less than $1 million in average annual sales), until September 2018. Large companies dealing with animal food also have until September 2016 to implement the current Good Manufacturing Practices (cGMP) requirements of that rule. In addition, FDA intends to implement, "as soon as possible," the third-party auditor certification program for U.S. importing companies, regardless of size. That final rule was published in November 2015. The other FSMA rules have staggered deadlines, but companies will generally have between one and three years following publication to comply, depending on their number of employees or average annual sales volume.

Among the five published regulations, the two preventive controls and the produce safety rules will impact most food companies directly. Generally speaking, FDA-registered food facilities must establish and maintain food safety systems that include a Hazard Analysis and Risk-Based Preventive Controls, or HARPC, plan, similar in many ways to Hazard Analysis and Critical Control Points, or HACCP, plans for juice and seafood. To verify the controls are effective, companies must monitor, test, take corrective actions, verify, and document the outcomes. Manufacturing and processing facilities must also maintain risk-based supply chain programs for raw materials and ingredients and provide cGMP education and training to their relevant employees.

Among the five published regulations, the two preventive controls and the produce safety rules will impact the majority of food companies directly.

FDA plans to work with public and private partners to develop and deliver training curricula. These will become standardized yet remain flexible. FDA will rely on existing alliances to develop training programs for domestic and foreign businesses. USDA is also providing grants to establish regional centers for food safety and training for small- and medium-sized farms and for fresh fruit and vegetable wholesalers. "One size doesn't fit all. The most important goal that the FDA expects of any training program is the outcome—that it advances knowledge among the food industry to meet FSMA requirements," the agency says.

The produce safety rule impacts growers of fruit and vegetables intended for raw consumption. Here, growers will be required to adopt science-based microbial testing and standards for water used for irrigation. The rule also elaborates on standards for manure application and composting. (The preventive controls rule clarifies when a farm is covered by produce safety rule and when its activities may place it under preventive controls jurisdiction.)

FSMA grants FDA access to company records during routine inspections. Should problems arise, FDA will first seek voluntary corrections at the facility level. If that fails, the agency will use its enhanced administrative powers, such as detention and mandatory recalls, and only afterwards seek court-ordered injunctions, seizures, or criminal prosecutions. Overall, FDA hopes to encourage industry compliance through education and technical assistance by partnering with other federal, state, and local agencies.

Filling Science and Technology Gaps

To successfully implement FSMA, FDA needs to fill "critical knowledge gaps" to support its regulatory decision-making. According to a strategic plan for 2015-2018 prepared by the agency's Center for Food Safety and Applied Nutrition (CFSAN), which is tasked with implementing FSMA, the knowledge gaps span several areas, including intervention and preventive control strategies for microbial and chemical hazards; development of improved field laboratory screening methods for contaminant detection; and advancing bioinformatics. CFSAN "is focused on setting science-based preventive control standards for the way industry

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produces, distributes, and markets food in order to strengthen the nation's food safety system," the CFSAN report states.

For several years FDA, CDC, and other agencies have been successfully utilizing full-genome sequencing and other genomic tools to identify pathogens implicated in foodborne outbreaks, including the recent Blue Bell *Listeria* situation. "We will see more of this in 2016," Dr. Acheson predicts, as FDA inspectors collect environmental swabs during routine inspections and the genomic sequences are stored in online databases. "It's almost like a criminal DNA database for later cross-referencing," Dr. Acheson says. "And should inspectors find a positive sample, there may be short-term consequences for the plant, including the issuance of a Form 483 for objectionable conditions," he says.

Budget Shortfall

A major ongoing problem is the lack of funds to implement FSMA rules. "FDA funding is the leading challenge in 2016," notes Craig W. Henry, PhD, vice president for global business development, Americas, Decernis LLC. "Funding is well below what was projected and required to move forward with FSMA regulations." FDA has requested $109.5 million in additional FSMA funding from Congress for fiscal 2016, which began Oct. 1, 2015. But the House allocated only $41.5 million and the Senate granted $45 million. And for the fourth consecutive year, both chambers rejected the agency's requests for industry user fees, this year totaling $191.8 million in food facility registration and inspection fees. FDA's proposed fiscal 2017 budget request will be presented to Congress in February 2016.

"If we receive [the requested] funding, we can move forward to implement this new, modern system in an effective and timely

way," said Taylor. "If we do not get the funding, we will lose momentum, and implementation will be badly disrupted." The ongoing budget challenge is confronting not only FDA, but also USDA, CDC, and state and local agencies responsible for food inspections and public health surveillance. "If states are expected to implement the regulations and have their enforcement plans executed, they will have to be funded and everyone will have to be in lockstep with the training that is required for all inspectors," Dr. Henry explains.

This funding shortfall may also slow FDA's issuance of guidance documents, which industry relies on to adopt the new regulations. Agency officials expect to release guidance documents for the preventive control rules by the end of the first quarter of 2016, which would give large companies only nine months to prepare. But these may also be delayed by politics. "In my experience in Washington, once you hit May in an election year you start walking through quicksand and you grind to a halt by July and August," says Dr. Acheson.

The bottom line is that "industry has to be ready in 2016," Dr. Henry tells *Food Quality & Safety*. "Things will become clearer once we see how the agency undertakes inspections after Sept. 30, 2016."

Criminal Prosecutions

Building on successful criminal prosecutions of Peanut Corporation of America (PCA) and ConAgra Foods Inc., the Department of Justice in 2016 will likely pursue additional high-profile cases against company officials when food safety problems arise. In September 2015, former PCA CEO Stewart Parnell was sentenced to 28 years in prison for his role in the 2008-2009 *Salmonella* outbreak that killed nine people and sickened more than 700 others nationwide. It was the stiffest punishment ever handed down in a foodborne illness case. His brother, Michael Parnell, was sentenced to 20 years, and the plant's former quality control manager, Mary Wilkerson, was sentenced to five years.

...the Department of Justice in 2016 will likely pursue additional high-profile cases against company officials when food safety problems arise.

These sentences "demonstrate the consequences for those whose criminal actions threaten that trust by introducing contaminated food into the marketplace," said Stuart F. Delery, acting associate U.S. attorney general, at the time of sentencing. "Americans expect and deserve the highest standards of food safety and

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integrity," added Stephen Ostroff, MD, acting FDA commissioner. "Those who choose profits over the health and safety of U.S. consumers are now on notice that the FDA, working with the Department of Justice, will strive to use the full force of our justice system against them."

Speaking at the American Food Manufacturing Safety Summit in Dallas in June 2015, Delery explained that the Justice Department will generally pursue felony charges against food company executives when it believes they acted intentionally. "A common thread in many of the cases we have pursued is that multiple people within an organization saw red flags of unsafe practices and chose not to act," he explained. "Even a single decision to cut corners can have deadly consequences." But when intent is not a factor, such as with Jensen Farms cantaloupes contaminated with *Listeria monocytogenes*, the government will generally pursue misdemeanor charges, he explained. (Eric and Ryan Jensen each received five years probation and were ordered to pay $150,000 in restitution.)

In May 2015, ConAgra Grocery Products LLC agreed to pay $11.2 million in a misdemeanor plea agreement to resolve allegations that it shipped *Salmonella*-tainted peanut butter under its Peter Pan brand and Wal-Mart Stores, Inc.'s Great Value label. More than 700 people were sickened in 44 states, with about 20 percent of them requiring hospitalization; none died.

More Rules: Gluten-Free Labeling

The U.S. FDA released a proposed rule in November to establish requirements for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients, and have the "gluten-free" claim. The rule, titled "Gluten-Free Labeling of Fermented or Hydrolyzed Foods," pertains to foods such as yogurt, sauerkraut, pickles, cheese, green olives, vinegar, and FDA-regulated beers.

In 2013, the FDA issued the gluten-free final rule, which addressed the uncertainty in interpreting the results of current gluten test methods for fermented and hydrolyzed foods in terms of intact gluten. Due to this uncertainty, the FDA has issued this proposed rule to provide alternative means for the agency to verify compliance.

The proposed rule, when finalized, would require manufacturers to make and keep records demonstrating assurance that: the food meets the requirements of the gluten-free food labeling final rule prior to fermentation or hydrolysis; the manufacturer has adequately evaluated its process for any potential gluten cross-contact; and where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.—*FQ&S*

Social Media

Traditional disease surveillance systems capture only about 20 percent of the estimated 48 million annual U.S. foodborne illness cases because only a small proportion of sickened people will seek medical care or report their conditions to authorities. Researchers have found that social media, such as Twitter and online review sites such as Yelp, can help local public health departments identify and track foodborne illness outbreaks more effectively.

Biostatistician Elaine Nsoesie, a research fellow in pediatrics at Boston Children's Hospital, and colleagues compared reports of foodborne illness posted on social media to those confirmed by the CDC. They found "significant correlations" for illnesses associated with poultry, leafy lettuce, and mollusks. "Online reviews of food service businesses offer a unique resource for disease surveillance," Nsoesie said in a presentation at an American Statistical Association's conference in August 2015.

Social media may even become a tool to help consumers learn more about their food. "We live in a highly connected world today where the consumer is more aware and empowered to learn about the origins of their food, recall alerts, and ingredients that they believe may cause them harm," says Angela Fernandez, vice president of retail grocery and food service at GS1 US. "In 2016, I believe we'll see fewer barriers between supply chain partners as they work to enhance traceability processes that make the recall process and entire supply chain more interoperable and collaborative," Fernandez tells *Food Quality & Safety*. "This proactive approach puts consumer concerns at the forefront." ■

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Special Report

Got Regulations?

The fast-growing legal cannabis industry is striving to ensure its edible goods are produced according to proper safety standards

BY **LINDA L. LEAKE, MS**

Imagine being informed by your local city health department that you are *not allowed* to include a nutrition facts label on the popular products you make and sell for human consumption. Julianna Carella faced that very problem relative to the gourmet snack items she produces at her Oakland, Calif.-based business, Auntie Dolores Kitchen.

"In 2010 the San Francisco Department of Public Health (SFDPH) told us we had to take the nutrition label off our products," says Carella, the company's founder and CEO.

Imagine further that, even though you're turning out pretzels, assorted cookies, glazed pecans, chili lime peanuts, cheese biscuits, caramel corn, and fudge brownies for retail sales, your manufacturing facilities and products are not subject to any state or federal food laws, regulations, or inspections. Not for now, anyway.

You see, most all of Carella's goodies contain cannabis, a.k.a. marijuana, a regulated Schedule I (a.k.a. Class I) narcotic.

Cannabis is sometimes used to reduce nausea and vomiting during chemotherapy, to improve appetite in people with HIV/AIDS, and to treat chronic pain. Knowing this, the aforementioned company name makes total sense. Carella is quick to clarify that, no, she doesn't have a beloved aunt named Dolores. Rather, she explains, Auntie Dolores is a play on "anti dolores," with "anti" meaning against and "dolores" being the Spanish word for pains.

"Since the beginning of our business, which was in 2008, our products have not been considered food, nor have they been considered medicine," Carella points out. "They are just considered cannabis."

That's why the SFDPH forced Auntie Dolores to remove the nutrition labels.

"We urged the SFDPH to allow us to keep the labels because sick people eat our products, including diabetics and cancer patients with specific dietary needs, and they need to be able to read and understand what exactly is in them to get the appropriate dose of THC (tetrahydrocannabinol), the primary active substance in cannabis," Carella relates. Most importantly, a scrupulous cannabis product label will include the THC content in milligrams (mg).

Cannabis foods, more commonly known as edibles, are made with an herbal or resin form of cannabis as an ingredient. These foods are consumed as alternate means to experience the effects of cannabinoids without smoking or vaporizing cannabis or hashish.

Carella says that, along with being one of the first edibles companies in California, Auntie Dolores was the first such Golden State entity to put a nutrition label on its products. "We convinced our city health department to allow us to leave the labels on because we feel consumers have the right to know this information," she relates.

The label issue was resolved within three months, Carella reports, emphasizing her respect for the SFDPH.

What About HACCP?

According to the SFDPH, no edibles requiring refrigeration or hot-holding shall be manufactured for sale or distribution at a medical cannabis dispensary due to the potential for foodborne illness. Exemptions may be granted by the SFDPH on a case-by-case basis. For such exempted edible cannabis products, ice cream and other dairy products for example, SFDPH may require a Hazard Analysis and Critical Control Points (HACCP) plan.

The FDA currently holds no jurisdiction or power over U.S. commercial edibles, which are allowed to be produced and sold in some states courtesy of specific state statues. Nonetheless, Auntie Dolores follows basically all of the food safety measures any food company would implement, Carella says. "We use a HACCP plan, even though our products don't require refrigeration or hot-holding," she boasts.

With a staff of 20 people, including six to eight in production, Auntie Dolores operates out of two rented facilities in confidential locations, manufacturing more than 5,000 units of product per month. As an example, a canister 5 inches in diameter containing 30 sugar-free, low glycemic pretzels counts as one unit. "Each pretzel

is designed to individually deliver an optimal dose of THC, with a full mg content of 120 mg THC per canister of pretzels," Carella relates.

Carella purchases cannabis plants and extracts from a local cooperative of growers. Auntie Dolores is actually part of this cooperative. "Anybody that touches the plant, from growers to manufacturers in our kitchen, to retailers and documented patients, are considered members of our cooperative," Carella explains.

Auntie Dolores edibles are sold in more than 250 of the estimated 2,000 licensed dispensaries throughout California.

Product Testing

Legalization of medical cannabis has allowed the laboratory testing of medicinal cannabis products. Any testing of cannabis or cannabis products must be conducted at labs in the states where they are produced. "Some of the biggest potential contamination concerns during cultivation or extraction are pesticides, heavy metals, mycotoxin, and aflatoxins," Carella says.

"California edibles producers are not required by law to do ingredient and finished product testing, but many dispensaries require testing," she adds. "We do ingredient testing and finished product testing to determine microbiological safety and proper potency."

Individual state requirements for cannabis traceability, quality assurance, and laboratory testing and monitoring requirements are definitely on the rise in legal cannabis states, says Patrick Vo, MS, MAcc, CEO of BioTrackTHC, a software company that serves the cannabis industry.

"Regulations, especially those addressing traceability, are crucial for advancing the cannabis industry, performing recalls, and improving product quality and safety," Vo emphasizes. "As more states adopt a centralized traceability system, food safety will improve for edibles."

California Dreamin': Change is Comin'

In the long-standing absence of detailed regulations and guidelines for its legal state medical marijuana industry, some California cities besides San Francisco have been making their own laws to oversee the manufacture of cannabis edibles, Carella says. However, this regulatory hodgepodge is about to change for California edibles manufacturers, as well as the state's entire cannabis industry.

On Sept. 11, 2015, California passed three key pieces of legislation relative to medical marijuana. As a result, effective in 2016, California will (finally) have a highly scrutinized, fully functional medical cannabis industry, subject to stringent regulation of all components of the chain from plant growers to dispensaries, including edibles manufacturers.

Specifically, Assembly Bill (AB) 266 will establish uniform health and safety standards for medical marijuana, including quality assurance (testing) standards to be enforced by local code enforcement offices. AB 243 regulates cultivation of marijuana plants, including use of pesticides. And Senate Bill 643 creates a new Office of Medical Marijuana Regulation to regulate how cannabis is grown and sold and to set fees and license businesses. Cities and counties will enforce the regulations and can choose to create their own marijuana sales taxes.

"Regulations will be good for us," Carella says. "We had no regulatory climate before and now we do. Without that, manufacturers are self-regulating, creating public health issues. In comparison, Colorado has strict rules to produce edibles, but California, no. Here anybody can produce edibles in a dirty basement or garage with no enforceable standards. And many companies are less than scrupulous with their product labeling procedures."

Cannabis Use Laws

In 1996, California voters passed Proposition 215, making the Golden State the first in the union to allow for the medical use of marijuana. While marijuana remains illegal federally, a total of 23 states, the District of Columbia and Guam now allow for comprehensive public medical marijuana and cannabis programs as of Sept. 14, 2015.

Only four states, Colorado, Washington, Alaska, and Oregon, plus the District of Columbia, have legalized marijuana for adult use (and also medical use).

There were 1.5 million purchasers of legal cannabis in the U.S. in 2014, according to the "State of Legal Marijuana Markets 3rd Edition Executive Summary," published in 2015 by the ArcView Group.

Fastest Growing Industry in America

In 2014, according to the aforementioned executive summary, the legal cannabis industry expanded 74 percent to reach $2.7 billion in combined retail and wholesale sales, and thus firmly established itself as "the fastest growing industry in America."

On the downside, Cannabis's Schedule 1 narcotic status presents a major roadblock for those in the industry who seek financing. "Banks insured by the FDIC will not typically lend openly to cannabis companies for fear of repercussion from the government," Carella explains. "And because of 26 U.S.C. 280E tax regulations, cannabis entrepreneurs are not allowed to write off many of the usual operational expenses incurred in more traditional businesses."

Despite the financial, legal, and regulatory challenges associated with cannabis, Carella jumps at any opportunity to extol her high (no pun intended) level of satisfaction with a career in the edibles industry.

"It's really fantastic to help people with their health problems," Carella says, "and to get them to eat, rather than smoke, cannabis, which is healthier. We get lots of testimonials, which is very rewarding. The positive feedback keeps me and my team going." ■

Leake, doing business as Food Safety Ink, is a food safety consultant, auditor, and award-winning journalist based in Wilmington, N.C. Reach her at LLLeake@aol.com.

For bonus content, go to December/January 2016 issue on www.foodqualityandsafety.com and click on "Ensuring Safety of Marijuana Edibles."

Safety & Sanitation

SANITIZING

The Basics of Sanitation for Any Food Facility

An introduction to understanding the differences between sanitizing and disinfecting, and how to select and use the proper sanitizer

BY **DALE A. GRINSTEAD, PHD**

The CDC estimates that each year roughly one in six Americans (48 million) get sick, 128,000 are hospitalized, and 3,000 die of foodborne illnesses. This often occurs because the human eye cannot see bacteria that can collect on food preparation, storage, and serving areas.

A food facility is any facility that prepares, stores, packages, or serves consumable food items, and can include restaurants, distribution centers, meat packaging plants, and more. These facilities have a responsibility to protect the people who consume their products. Proper sanitation prevents the spread of bacteria and reduces the chance that consumers will contract a potentially deadly or debilitating foodborne illnesses.

To Sanitize or Not?

Employees who are responsible for cleaning need to understand the difference between disinfecting and sanitizing, and how to properly sanitize surfaces. Disinfectants and sanitizers are not interchangeable and are intended for very different purposes. According to the U.S. EPA, disinfecting is intended to destroy or irreversibly inactivate all infectious fungi and bacteria, but disinfecting does not kill spores on hard or inanimate surfaces. Sanitizers are not meant to kill all microorganisms, but rather reduce the number of microorganisms to a safe level. In some cases, disinfectants can be used to inactivate viruses on surfaces, whereas sanitizers cannot be used to eliminate viruses.

Sanitizers have a lower level of antimicrobial efficacy than disinfectants, and they are safe for use on food surfaces. In general, any surface that comes in contact with food needs to be sanitized. Any sanitizer used needs to be approved for use on that surface and should not be corrosive. An exception to the use of sanitizers is if there is a concern that a surface may be contaminated with a virus, such as Norovirus. In this case, surfaces should be cleaned, rinsed, disinfected with a disinfectant that is registered with the EPA as being effective against the specific virus of concern, rinsed once more, and then sanitized as normal.

Although there are no regulatory requirements from the FDA regarding floors and other non-food contact surface sanitation, it is good practice for food facilities to have a microbial control process in place to reduce the risk of cross-contamination from such surfaces.

It is important for food facilities to use the appropriate antimicrobial agents. When disinfectants are used on surfaces where sanitizers should be used instead, food facilities run the risk of contaminating food with antimicrobial agents. It is also a violation of federal law to use antimicrobial agents in a manner that is inconsistent with their labels, a practice known as "off-label" use. This "off-label" use would include using a disinfectant when a sanitizer should be utilized. Product labels provide directions for the type of surfaces a solution can be used on, as well as instructions for use.

Selecting a Sanitizer

When selecting a sanitizer, it's important to choose a product that is EPA registered. Check the label to make sure the sanitizer is effective against the organisms of concern. It is also crucial that the sanitizer is compatible with the equipment being sanitized. For example, if a surface is aluminum or cast iron, a chlorine sanitizer may not be appropriate as it can cause corrosion.

It is also recommended to select a simple and safe dosing system to use with the sanitizer in order to prevent employee contact with concentrated chemicals and ensure the sanitizer is correctly diluted each time. Working with knowledgeable chemical suppliers is valuable when selecting sanitizers because they can provide

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recommendations, clarify what the sanitizer will and will not do, and offer training.

Using a Sanitizer

Employees need to undergo training in order to avoid the consequences associated with improper sanitation. Improper sanitation can cause food processed or prepared within a facility to become contaminated with unwanted microorganisms. This could mean contact with spoilage organisms that cause food to have a shorter shelf life or flawed flavors and odors. Cross-contamination can also cause food to come into contact with pathogenic organisms that can result in illness and, in serious cases, death.

If it appears that a sanitizer is not working properly, it's likely that the cleaning and rinsing process preceding the sanitation step was inadequate. Cleaning chemicals that are not rinsed off of a surface can inactivate some commonly used sanitizers. An employee who has not been properly trained may be tempted to use "extra" sanitizer to ensure bacteria are removed. Unfortunately, the use of extra sanitizer is wasteful, can be hazardous to use, damaging to waste or water systems, and can be a misuse of the sanitizer—which violates federal law. Sufficient cleaning combined with the recommended concentration of sanitizer will be effective in sanitizing the facility.

It's also important to note that the frequency of surface sanitizing varies. According to the FDA's Food Code, non-refrigerated surfaces must be cleaned and sanitized at least every four hours. More frequent cleaning and sanitizing may be needed depending on what food is being processed and if there are changeovers from one food to another. A food contact surface should be exposed to the sanitizer for at least 60 seconds (or whatever time is specified on the EPA-approved label) before being allowed to drain completely and air dry. Much of the equipment used during food processing and preparation is complex and may need to be disassembled for cleaning. Such equipment should be disassembled according to the manufacturer's instructions then cleaned, rinsed, and sanitized. After the pieces have been allowed to air dry, equipment should be reassembled and re-sanitized after assembly. The equipment should completely air-dry before it is used to process food again.

Overall Protection

Contaminated food can result in costly recalls, negative publicity, and lost business. It's sometimes impossible for a business to fully recover from these consequences. Thus, it's important for every food facility to maintain the highest cleaning and sanitation standards in order to preserve brand reputation. Understanding the difference between sanitizing and disinfecting, and best practices for selecting and using sanitizers, protects employees, customers, and brand reputation by reducing the risk of potentially deadly outbreaks. ■

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Vigilance: The Best Weapon Against *Listeria*

Considerations for managing *Listeria monocytogenes* in food processing require diligence, flexibility, and being attuned to the latest scientific findings

BY **R.L. PETRAN, PHD**

I'm not sure you can say that *Listeria monocytogenes* is pathogen enemy number one, but it's definitely on the most unwanted list. It can be virtually everywhere, and there is growing public awareness of what it can do when left unchecked. The recent news about recalls only reinforces what many of us already know—an outbreak is possible, traceable, and has very real consequences for both business and consumers.

Background

Listeria monocytogenes, commonly referred to as *Listeria*, is a pathogen that causes listeriosis, a serious human illness that is fatal in about 20 percent of cases. Unlike most other foodborne pathogens, it can grow at proper refrigeration temperatures. In addition, *Listeria* is widely distributed in nature; the organism has been recovered from farm fields, vegetables, animals, and other environments such as food processing facilities, retail stores, home kitchens, and ready-to-eat foods.

As the graphic on page 31 shows, understanding the ecology of *Listeria* is the first step to its management and ultimately, to protect public health. This understanding can help identify the optimal control measures, effectively aimed at the most likely sources of the organism to keep them in check.

It's incumbent that any controls be validated to demonstrate their effectiveness, then implemented consistently and routinely verified to ensure that they are carried out as expected. As new information becomes available about *Listeria* and its possible sources, these controls may need refining.

Considerations for Management

So what can you do to effectively control *Listeria*? The short answer: remain vigilant and focused on continual improvement. Here are some considerations for effective management of *Listeria*.

***1. Know your enemy, i.e. understand the ecology of* Listeria.** Keep in mind that this information must be refined as new facts emerge. You can't effectively manage a pathogen without a complete understanding of what it is and the environment in which it thrives. *Listeria* has been isolated from a wide variety of raw agricultural products including raw meats, poultry, seafood, and milk. It is found in soil and in silage and persists in nature and in processing environments in niches where it can evade control mechanisms. It can also sometimes be enmeshed in biofilms where the cells may be protected from the effects of sanitizers.

Parameters for growth of the organism allow it to thrive under conditions that are more extreme than what other pathogens may be able to stand. According to International Commission on Microbiological Specifications for Food, *Listeria* cells are able to grow over a temperature range of 32 degrees Fahrenheit to 113 degrees Fahrenheit, a pH range of 4.4 to 9.4, and a_w limits from 0.92 to 0.992. This means that *Listeria* may be a hazard in foods containing higher levels of salt or sugar and in refrigerated items.

Listeria is a persistent organism. R.B. Tompkin reported survival in dairy facilities as long as seven years; in a fish processing plant, four years; and in a poultry facility, up to 12 years. Further evaluation of the literature reveals that the concept of persistence is complex and requires greater scrutiny of the data in the context of the actual production environment. What has emerged is that a clearer understanding of the food environment is needed for optimal control. Because *Listeria* is abundant in nature and can be found almost anywhere, there can be a constant reintroduction of the organism into the food plant, retail setting, food service establishment, and home. It is difficult to totally eliminate this contaminant from the food-handling environment, but the goal is to control it as effectively as possible, especially where it can contaminate ready-to-eat, refrigerated foods.

2. Identify controls to manage* Listeria *sources. The greater the ability of a food to support growth of *Listeria*, the greater the risk. The relatively small proportions of foods that may be contaminated with high levels of *Listeria monocytogenes* pose the greatest risk. Contributing factors to overall listeriosis risk include consideration of the:

- Ability of the food to support the growth of *L. monocytogenes*;
- Amount and frequency of consumption of a food;
- Frequency and extent of contamination of a food with *L. monocytogenes*;
- Temperature of refrigerated/chilled food storage; and
- Duration of refrigerated/chilled storage.

Key to effective risk management is consistent application of *Listeria* control measures.

One measure is prevention of growth through time/temperature control or formulation control. Intrinsic characteristics of a food (e.g., pH, a_w) can be leveraged in the product development process to build in effective growth controls. Prevention of growth is essential; *Listeria* can grow at refrigerated temperatures, which defeats one of the traditional food safety measures. However, the organism is killed by normal food pasteurization and cooking processes, and is typically sensitive to most sanitizers when used at recommended rates and as long as it is not shielded within biofilms. Still, contamination may occur after the cooking process in the processing environment, at retail locations, and in the home. For example, post-pasteurization contamination of food products can occur when the organism is dispersed via an aerosol.

The other essential part of effective control is prevention of contamination of the food through all aspects of the food handling process. This starts with preventing entry of the organism by controlling incoming contamination that can originate with employees, equipment, ingredients, and packaging. Movement of people, equipment, materials, etc., must be monitored, controlled, and restricted as appropriate. Preventing growth in the food handling areas relies on the removal of growth nutrients, including water and soil. Keep areas as dry as possible, keep temperatures low, and have sound sanitation practices. Appropriate sanitation programs include the following considerations.

For Cleaning:

- Match the cleaner to the nature of the soil;
- Match the cleaner to the water properties;
- Optimize solution compatibility with the surface;

- Ensure the cleaner is appropriate for the method of application;
- Use products that meet environmental guidelines;
- Follow sanitation standard operating practices; and
- Seek guidance from sanitation providers.

For Sanitizing:

- Use EPA-registered products that have a claim against *Listeria monocytogenes* on the label; and
- Follow the manufacturer's labeled instructions.

In addition, knowledge of potential harborage sites is important, as contamination is more likely to occur when the organism has become established in a niche where it may be able to evade control measures. Good sanitary equipment design and proper maintenance, in combination with regular, effective, and thorough sanitation, can help eliminate *Listeria* from niches. Targeting sanitation to the areas where *Listeria* can be harbored is essential. Food processing plant surveys have found *Listeria* in the following locations: floors, drains, coolers, cleaning tools, product and/or equipment wash areas, food contact surfaces, condensate, walls and ceilings, and compressed air.

Since it's essential to detect and manage harborage sites with thorough and frequent sanitizing to control *Listeria*, a program should include daily sanitation of floors and drains and adequate attention to less frequently cleaned areas such as HVAC systems, walls, coolers, and freezers. Also, damaged equipment, cracks, crevices, and hollow areas must be part of sanitation and inspection schedules. It is essential to avoid creation of aerosols during cleaning, especially of floors and drains, to avoid spread of contamination.

Finally, controlling *Listeria* also means considering the roles of various transmission routes. The same vectors that can bring *Listeria* into a facility also need to be controlled once they are inside. These include employees, forklifts, cleaning tools, pests, water, air, etc.

3. Validate the effectiveness of controls. Any control measure implemented with the intent of managing *Listeria* needs to be chosen carefully and shown to be effective. This is the crux of validation and involves the act of collecting and evaluating scientific and technical information to determine that the control measure, when properly implemented, will achieve the intended result.

For *Listeria* control, this can come from a variety of sources such as scientific support, including published studies or references; advice from experts including food safety personnel, academics, consultants; and/or in-plant expertise gained from extensive experience. These resources can help assess whether the considered control is theoretically sound. But, the validation process needs to go a step beyond these scientific principles or advice, and must extend to studies demonstrating that the control can be implemented at the site per the plan to achieve the intended results. Evidence must show that the control can be effectively implemented as designed.

This latter part of validation gets at the practical aspects of a control program, answering this critical question: how capable are the facilities at impeccably implementing the controls? In this part of validation, one needs to determine how to apply scientifically sound information to the particular process and plant. Possible considerations might include the availability of personnel to carry out the control, their level of expertise, the tools that might be needed, the type of equipment available, the age and condition of the facility, etc. This requires in-plant data collection, test results, and other information demonstrating that the control can be operated within the particular establishment. The USDA Food Safety Inspection Service offers practical guidance on validation.

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4. Implement the controls. Once controls are identified and determined to be valid, they need to be continuously practiced, regardless of the operational or facility-specific factors that might affect them. Meaning, sales are up and you want to make more of a particular food product? Great, but the controls and practices cannot change. There needs to be continuous attention to these control mechanisms since they are directed against a serious potential hazard. This is the crux of establishment and practice of a food safety culture. A rule of thumb is to ensure that there is support to continually practice the control measure "irrespective of who's looking!"

Leadership is essential. Senior management must provide appropriate resources including personnel, supplies, materials, etc. to carry out the controls. In addition, they need to offer support to the various team leaders and members to emphasize the importance of strict attention. Management must be engaged and keep employees well informed of the potential extent of the *Listeria* hazard and underscore the importance of the team's work to actively manage the risk.

5. Verify that controls are consistently applied and be ready to modify them if needed. A key part of implementation is to verify that the system is operating according to the pre-determined plan. This is verification and this practice must be applied to every specific control measure to ensure that each is applied according to design. It allows for ongoing assurance by the plant that the control was done as designed.

There are many ways to verify. The particular facility needs to determine which procedure is best for its operation. Fresh eyes can help, so a review of records by someone other than the individual who recorded the results is a common practice. Another way is thermometer or water activity meter calibration or ensuring that plant equipment used for cooking is adequately set up. Sanitation verification that the surface is free of sensory detectable soils may be done via inspection for visual cleanliness or by sight, smell, or feel. Other sanitation verification practices include swabbing for residual adenosine triphosphate (ATP) after the cleaning step to show that the surface is free of detectable animal, plant, microbial, or human ATP.

Microbiological swabbing is also commonly used to verify effectiveness of sanitation. It should be done just after the sanitizing step or immediately before manufacturing if there is an extended time during which the sanitized equipment sits before production startup. Microbial swabbing could also be done at other times to identify *Listeria* harborages and allow for prompt implementation of appropriate corrective actions. Recently published guidance documents from Grocery Manufacturers Association and United Fresh Produce Association provide excellent information to help direct the development of a comprehensive *Listeria* swabbing program and provide input on the necessary corrective actions that could be followed. Although *L. monocytogenes* is the only member of the *Listeria* family that causes human illness, the presence of *Listeria* species in a food processing or handling environment may indicate that conditions are favorable for *L. monocytogenes* and appropriate actions should be taken.

Over time, things change in a processing plant and *Listeria* controls need to be validated regularly to ensure they remain effective. Data collected from regular verification should be input to this process. Consider any significant changes that may impact these controls and prompt re-validation of the controls. This typically includes changes in formulation, production processes, equipment, scientific information, staffing, and water (source or season).

Research in Phage Treatments

"*Listeria monocytogenes*: A Target for Bacteriophage Biocontrol," featured in the November 2015 issue of Comprehensive Reviews in Food Science and Food Safety, focuses on the use of bacteriophage biocontrol to target *L. monocytogenes* in the food industry, specifically direct application of the bacteriophages to food products. The article includes discussions on the many factors that influence the success of these treatments, such as the food matrix itself and the bacteriophages used in the treatment. Liquid food products are treated more successfully, probably due to dispersal of the phages and treatment with higher phage titers always tend to have better results.—*FQ&S*

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Conclusion

Effective management of *Listeria* requires awareness of the particular characteristics of the organism and identification combined with ongoing diligent practice of valid controls to address its potential risks. Such actions must be verified and constantly assessed to ensure that they are continuing to make a difference.

The process of identifying and implementing the optimal measures needs |to be reinitiated if there is sufficient evidence through swabbing or other data such as new information obtained from outbreaks, published research, or regulatory commentary that indicates a possible loss of control. *Listeria* control requires unwavering and strict attention to many factors to ensure that it remains effectively managed. Not to be discouraged, it's challenging but essential.

As they say, the proof is in the pudding. Or in this case, what's *NOT* in the pudding. ■

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OSHA Compliance Prevents Workplace Dangers

Process Safety Management can help handle risks associated with using highly hazardous chemicals in food industry

BY **BOB STEFFENS**

Since its inception, the U.S. government's Occupational Safety & Health Administration (OSHA) has been concerned with regulating food industry safety from many different directions. However, it was only in the 1990s that the agency brought its regulatory powers down hard in a new area: Process Safety Management (PSM). In turn, PSM's impact continues to resonate throughout wide-ranging industry sectors, with food and beverage being no exception.

Shifting Gears in Safety Focus

OSHA's creation and implementation of PSM was a bold move in a new direction. Not targeting the processing, distribution, or retail sales of food and the risks involved with these different stages, PSM charted its own course. It is all about the use, storage, manufacturing, or handling of highly hazardous chemicals (HHCs). And OSHA drew an important distinction in not addressing low-chemical exposure.

What triggered this sudden attention to HHCs? As is often the case, disasters make more of a statement than numerous proposals, speeches, and lobbying combined. In a relatively short time period, there were several chemical explosions that resulted in death and injury. Union Carbide's 1984 methylisocyanate gas leak, which killed approximately 2,000 people in Bhopal, India, was the most notable. Because of this and other U.S. incidents, OSHA has vowed to never let these kinds of chemical accidents happen again, at least in its national jurisdiction.

Getting Down to Business

PSM's goal is to prevent the release of toxic, reactive, flammable, or explosive chemicals and was implemented in the 1990s. HHCs represent the potential for a catastrophic event at or above the threshold quantity (TQ). In the food and beverage industry, the chemical of overriding importance is anhydrous ammonia, with a 10,000-pound TQ as being a "covered facility" under PSM regulations. However, walking a somewhat fine line, OSHA's enforcement policy is to not cite companies for violations if stored flammable liquids in atmospheric tanks are connected to a process. That is, unless the process outside of the storage amount contains more than 10,000 pounds of the substance.

PSM actions begin with compiling broad-based safety information; this process must precede the launch of the critical process hazard analysis (PHA). The purpose of PSM is to advise in advance, in a threefold approach, both employer and employees who operate the process about potential HHCs involved. One is specific hazards with mandatory information required ranging from toxicity to physical data to chemical stability data.

Two is the process technology, with required information including flow diagram, maximum intended inventory, and consequences of deviations. Three is about the process equipment, which requires more information than the first two above. Detailed descriptions must be provided on construction materials, electrical classification, ventilation system design, design codes as well as safety systems. Further, virtually every equipment characteristic must be documented, assuring it was designed and constructed to code and documenting that it is regularly maintained, tested, and operated safely.

With the properly compiled safety information in hand, the important PHA is next. It mandates a careful review of what could possibly go wrong and, after identifying those, companies must develop safeguards that can be implemented to prevent the release of HHCs. As could be expected, there is not a unique PSM procedure to follow for anhydrous ammonia in the food industry while specifying other separate procedures for each industry and type of business. With PSMs, "one size fits all" actually applies in terms of what must be done for regulatory compliance.

In the overall PSM procedural marathon not only must hazard identification be made and safeguards instituted but companies must also prepare written procedures, train employees, conduct safety reviews, evaluate critical equipment, and develop procedures for management of change. At the outset, however, the PHA must address process hazards, identify previous incidents with catastrophic potential and acceptable detection methods, and determine the possible outcome when engineering and administrative controls fail, where facility is located, human factors, and qualitative evaluation of possible workplace effects if controls do fail.

In OSHA's opinion, the analysis or evaluation i.e., PHA, is best accomplished by a team rather than an individual. The team should be knowledgeable not only in engineering but also in specific process operations, and one team member should have direct knowledge of each process being evaluated. Through a system, the findings and recommendations should be ad-

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dressed in a timely manner, and corrective actions should be completed as soon as possible and communicated to possibly affected employees. To stay current, the PHA should be re-evaluated every five years.

In the final phase of this PSM overview, the major target must be addressed: operating procedures of each covered facility (primarily anhydrous ammonia in the food industry). Eschewing bureaucratic language, OSHA states that "clear instructions" must be provided to workers that allow them to safely operate each covered process. These operating procedures safety mandates are in two categories: operating phase steps and operating limits. With injuries and possible fatalities at stake, much more than "Here's the on/off switch" qualifies as need-to-know information. Instructions in each operating phase, for example, include initial startup, normal operations, emergency shutdown/operations, normal shutdown, and start-up after a turnaround or emergency shutdown.

On the operating limits side of process safety information are a number of critical factors, which were developed to essentially cover all safety angles. These include describing what could happen with operational deviations and how to correct or avoid any and all safety and health issues; relevant chemical properties and hazards; necessary precautions and control measures; controlling HHC inventory levels and addressing any special or unique hazards; and discussing the safety systems and the function of each.

Beware of Incidents and Audits

Without drilling down into every single detail about PSM and its implementation, this overview (not intended as legal advice) shows the scope of what must be done. Leaving virtually nothing to chance, success depends on employee participation, training, contractor cooperation, pre-startup safety review, mechanical integrity of critical process equipment, management of change, incident investigation, emergency planning and response, and compliance audits.

In the daily workplace, what is the anhydrous ammonia risk? Consider OSHA's tally of anhydrous ammonia accidents dating back to 1999 and the initial reported exposure to an ammonia release. That was followed by 19 incidents in subsequent years ranging from exposures and various injuries to fatalities. Included are incidents of inhalation, spray in eyes, a 16-employee exposure to an ammonia release, two refrigeration technicians sustaining corneal burns, and a total of four workers killed in separate incidents. Those statistics make two points: regulation is necessary and even with regulation, incidents can still occur, making adherence to procedures that much more critical.

It's important to recognize that regulatory programs such as PSM revolve around resources, time, and money. By reducing an emphasis on any of these three, not surprisingly, the risk of causing a catastrophic release or being on the receiving end of a regulatory penalty is dramatically compounded. Additionally, to drive home how critically OSHA considers PSM, the agency does not provide partial credit for companies achieving incremental success. In other words, 100 percent compliance from day one is required.

Keep in mind that making compliance simple was not on OSHA's agenda. To underscore its stance, take note that a PSM safety auditor can ask a company more than 500 questions and can potentially issue that many citations for compliance performance. Increasing the difficulty, sometimes a question may comprise "nested" questions requiring multiple questions to be answered in order to satisfy one regulation. Companies may be audited at any time and OSHA selects the questions. Although it could theoretically ask all 500 plus questions, that typically is not the case but full compliance is still necessary.

Not a lightweight program, the fines for non-compliance are not insignificant either. Fines for individual workers may be as high as $250,000; for companies, $500,000 dollars. Although it may seem like actual release and outright injuries account for most or all the fines, not meeting necessary paperwork can also result in heavy regulatory penalties. Civil lawsuits and/or criminal liability may also come into play with violators.

Making PSM Work

Faced with a potentially catastrophic anhydrous ammonia incident, what's the best way for a regulated company in the food industry to get the edge? The solution is three-part and comes under the heading of Risk Mitigation.

One, a specialist is worth his/her weight in gold. At most companies, people with specific skillsets are hired for positions fitting that expertise. Some positions, however, are considered fair game for a "Jack of all trades, master of none." If a company has an individual filling its PSM coordinator position, it is usually the generalist. Unfortunately, experience has shown that PSM's wide-ranging complexity and scope cannot be met with minimum resources or personnel wearing multiple hats.

The solution, even if it stretches the company budget, is hiring a PSM coordinator who is preferably an engineer with a minimum five years' experience in the company's industry and, ideally, with regulatory management experience. Bringing that type of experienced individual onboard will pay dividends in the savings recognized from avoiding potential penalties and fines. If hiring in this job area is not familiar to HR, work with the department and/or recruiters to develop a staffing plan for a coordinator and, optimally, a team.

Two, companies in the food industry should develop a budget that does not cut so close that it barely covers what must be done. Before anyone envisions a gloomy projection, however, OSHA does not see excessive spending as necessary. In a company's initial five years of regulatory compliance, OSHA's estimate is that worst case—not typical, but worst—budgeting would be 1.1 percent for large companies and 3.2 percent for small companies. When preparing the budget, imagine that this money will have a real, everyday impact on workplace safety.

Three, above all, arrive at a solution that addresses all the company's requirements in a cost-effective way that works with the budget to accomplish compliance initiatives. Within this solution or plan is an emphasis on project management rather than dollars and cents to avoid penalties and ensure a safe workplace.

PSM is a real challenge but, when done right, it keeps a company at peace with regulators and reduces or eliminates workplace incidents, such as with anhydrous ammonia. ■

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BRC Global Standard Gets Revised

Updated standard includes review of all clauses to offer greater guidance to food companies and clarity to auditors | BY JOHANN-CAROL VON MALSEN

To be in compliance with consumer protection regulations, food manufacturers need to fulfill strict safety, quality, and operational criteria. The Global Standard for Food Safety, published by British Retail Consortium (BRC), provides a basis for fulfilling these criteria. BRC started to revise the standard in early 2014. The new version, Issue 7, was published in January 2015 and took effect in July of same year.

For the first time, BRC invited international certification bodies to the BRC headquarters in London to play a proactive role in the development of the standard. TÜV SÜD used the opportunity to contribute its practical certification experience to the new version of the standard in order to give future audits a more practical focus. The new version aims at reducing the burden caused by audits as well as susceptibility to fraud. In addition, it is designed to ensure greater transparency and traceability in the supply chain and improve food safety at small sites that are still in development. The requirements of the standard further include many minor changes regarding specified product authenticity and claims, management of outsourced processing, and packaging and subcontractor approval. The revised standard also introduces new requirements for the management of suppliers of raw materials and packaging as well as more specific requirements for agents and brokers.

Improved Transparency

To reduce the potential for product contamination, the standard defines two risk zones in the processing and storage facilities with different requirement levels of hygiene and segregation. New features of the standard are ambient high-care areas for products that do not require chilling and non-product areas, such as canteens, laundries, and offices. In the future, manufacturers also will have to define these areas. Issue 7 of the BRC standard introduces a stricter approach to exclusions from the certification scope. To exclude products that are manufactured at one site from the certification scope, organizations must ensure that these products are clearly differentiated from the certified products and produced in a physically separate area of the factory. In contrast to the previous version of the standard, products manufactured using different equipment but in the same production area can no longer be excluded from certification. The audit report has been extended to include an additional section for providing the reasons for any exclusion. The term "minority of products" is no longer used in the revised standard as it leaves too much room for interpretation and may cause misunderstanding.

New Grading System

The revised standard introduces a new grading structure and revised nomenclature. This modification ensures that relevant non-conformities are recorded in greater detail and to make the top grade more exclusive. The top grade of AA is only awarded if the audit reveals no more than five minor non-conformities and has the purpose of giving an incentive to engage in continuous improvement, even for manufacturers with excellent performance. In the lower segment, grade D was extended to stand for 25 to 30 minor non-conformities. The revised standard identifies the grades for unannounced audits with a "+" symbol added after the grade. BRC introduces the Global Markets Program, which makes initial certification easier for small suppliers and sites that are still developing their management systems for food safety. The Enrollment program has been revised so that audits are now offered at three levels. The starter audit, the Basic Level, is closely aligned to the Global Markets Program of the Global Food Safety Initiative (GFSI). The advanced program, known as Intermediate Level, is aligned to the higher requirements of the GFSI Global Markets Program. The highest level that can be achieved is full BRC certification.

As a matter of principle, the audits of the basic and intermediate level are carried out according to the same rules as a full BRC audit but with certain exceptions, such as restricted requirements and shorter audit duration. The organization does not receive a grade. The audit can only be passed or failed. Organizations receive a confirmation that they have fulfilled the requirements of the respective level. These confirmations are clearly distinguishable from a full BRC certificate. Companies can use the new system to successively approach full certification.

Interactive Information Platform

BRC has developed an online information management system that provides access to all content related to the Global Standard for Food Safety—from interpretation guidelines and support publications, webinars, case studies, and whitepapers to social media posts. Interested parties can also make use of the BRC Participate discussion forum and exchange certification-related ideas and experience with international colleagues. This service can keep consumers, certification bodies, trainers, and consultants up to date.

Outlook

Following the revision of the BRC standard, similar revisions can be expected for other food standards, such as the International Featured Standards (IFS) Food. IFS Food is a recognized standard for auditing the product and process safety and quality of manufacturers. The standard is being revised at present. Publication of IFS Food Issue 7 is expected by Jan. 1, 2017; it will become mandatory July 1, 2017. Companies that have already implemented the new requirements of the Global Standard for Food Safety should ensure they'll be able to respond appropriately to any revision. ■

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Checkers uses mobile, cloud-based business performance software to monitor store cleanliness, customer service, and regulatory compliance data at all 805 locations.

Preserving Your Restaurant Chains' Reputation

Best practices in conducting food safety audits to provide the information a franchise needs to engage corrective action

BY **DANA SLAGLE**

A restaurant's reputation may take years to build, but one customer getting sick, or worse, even dying, from a foodborne disease can destroy that reputation practically instantly—thanks to the blazing speed of social media. If the restaurant is part of a chain, the reputation damage is inflicted upon the entire chain bearing the name, not just one location.

One of the best preventative measures a restaurant can take is to make food safety audits an essential function of its operations. These audits help ensure customers against foodborne illnesses and provide the information restaurants need to undertake corrective action.

Auditing Benefits

Properly designed and implemented food safety auditing allows restaurants to:

- See how well compliance programs are being adopted in all locations;
- Close gaps in corrective action management and improve accountability and responsibility;
- Ensure effective communication with field operators on standards of quality compliance, delivery, and urgent directives;
- Enhance assessment programs as the business grows and changes and new quality demands are introduced;
- See the big picture and tell the story of what's really going on to key stakeholders; and
- Help field operators increase productivity while decreasing errors.

Audit Form Best Practices

Food safety audit forms should enable auditors to give a fair, objective, and consistent assessment of every restaurant. However, companies frequently sabotage their evaluation process with ineffective and inefficient forms. "Death by audit" occurs when organizations capture tons of data but then fail to create any actionable items related to said data.

Companies still stuck in the food safety auditing dark ages (those using Excel spreadsheets and/or pen and paper) tend to collect an abundance of data, but then let it disappear into the proverbial black hole. They may feel good for having done the audit, but unless the necessary corrective actions are executed, reputation and customers will remain at risk.

The following are eight best practices for a food safety audit form.

1. Make questions clear and concise. Food safety audit form questions must have great clarity and zero ambiguity. Auditors should *never* have to guess what an answer means. Examine your form carefully and make sure any ambiguities are removed. You want objectivity, not subjectivity, from the auditor.

For example, would the following question make sense on a food safety auditing form: Are the cinnamon rolls good? Obviously not. Questions about the taste of food don't belong on a food safety audit form. One person may love the way something tastes, but another may think it tastes horrible. A taste test is not a safety test. No safety issue is being addressed. Instead, ask specific questions about the temperature, color, storage, and size of the rolls.

Use graphics as another communication tool for the auditor. If you're looking for the temperature, include a bright, clean graphic displaying the proper temperature range. What should properly colored and sized rolls look like? Include pictures of those. This helps the auditor know exactly what to look for during the food safety audit process.

2. Build dynamic forms. Questions on your food safety audit form must provide sufficient information to drive change and spur corrective action. If your form is nothing but a giant yes/no checklist, get rid of it. It'll do you no good. The following are examples of questions that will not provide sufficient information.

- Is food stored in the refrigerator at the proper temperature?
- Are the bathrooms cleaned on a regular basis?
- Were customers greeted immediately upon arriving?

Yes, these may seem like logical questions, but all they're doing is scratching the surface. This is what's known as a "flat form" and will leave your operations people wondering, "Now what?" Instead, your audit form must be a "dynamic form"

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that also features relevant follow-up questions that provide essential, additional details. The best dynamic forms will be offered via cloud-based, mobile software—not via an electronic spreadsheet, and certainly not with a paper and pencil system.

For example, what if a trend emerges indicating a portion of the food is the wrong temperature? You need to be able to identify the root cause of this issue. Additional data should identify exactly which food is out of temperature, where this food is located, and the temperature of the food.

A dynamic form will offer about 20 different question types, allowing companies to customize the specific information their questions capture. The "question tree" is one of the most popular question types. Here's how it might work with the following question: Is food out of temperature? If this produces a "no" answer then the dynamic form automatically continues to the next question, bypassing any irrelevant follow-up questions. This timesaving feature creates a far more efficient audit. But if the answer is "yes," then a series of relevant questions automatically appear on the auditor's mobile device, such as: Which food is out of temperature? What temperature is it? Where in the restaurant is it located?

With this information, those responsible for executing any corrective action can see, for example, the potato salad in the walk-in cooler was 6 degrees too warm. Now the company can take corrective action by developing training for that restaurant on how to better maintain its walk-in cooler and how to prepare the potato salad to prevent it from not being maintained at the proper temperature.

3. Make correct answers consistent. As much as possible, make sure your correct answer choices are consistent throughout the audit form. In other words, a "yes" answer should indicate compliance and a "no" answer the opposite. Take the following questions for example.

- Are the bathrooms clean? Yes – correct, No – incorrect
- Is the ice machine clean? Yes – correct, No – incorrect
- Are there any pests in the facility? Yes – incorrect, No – correct

The last question should be changed to "Is the facility free of pests?" This will prevent confusion and create consistency. (Of course, as discussed in the previous point, your form should be dynamic and have follow-up questions to these yes/no questions!)

4. Have a logical scoring system. Well-formatted questions won't produce a fair assessment of the restaurant without a logical scoring system. Both are essential.

Critical violations must be clearly distinguished from non-critical violations on food safety audit forms. Make sure your scoring system for these two types of violations is logical. Think of it this way: Use points to make a "point." If a particular question is critical to your restaurant's operations, then assign it a high-point value. The auditor should know to give all points for compliance and zero points for failing to meet standards. Subjectivity from the scoring is eliminated.

Lastly, the established scoring system must be readily available on the food safety audit form. Auditors should be able to easily understand the scoring system so that there's consistency in scoring from auditor to auditor.

5. Provide relevant instructions to the questions. An audit form without any audit instructions is trouble. If the auditor has to rely on memory, you're opening yourself up to inconsistent evaluations. Make sure every question on your audit form has necessary evaluation guidelines, thus eliminating any guesswork.

6. Consider workflow when organizing questions. When determining the order of the food safety audit form questions, keep in mind the restaurant's logistics and workflow. Put yourself in the shoes of the auditor so that you can be certain the questions flow the way the restaurant was built. That assures the auditor will be able to efficiently conduct the evaluation one restaurant section at a time, instead having to jump back and forth.

7. Keep the list of questions short and relevant. The form questions must help you drive change and improve food safety. Make sure each question on the audit fits this goal. As you look over each question on your audit form, ask yourself, does this question track information that we need to drive performance? And, is this question still relevant to my restaurants?

8. Use an automated platform. This continues the previous discussion of using dynamic forms instead of flat forms (see No. 2 best practice). It comes down to conducting your food safety audits with the latest cloud-based, mobile software technology and leaving behind the old days of electronic spreadsheets or paper and pencil. The inconvenience of updating spreadsheets or paper forms will prevent you from making the critical changes that will keep your restaurant safe. Following up via email to keep everyone in the loop about policy changes is highly ineffective.

If you want to effectively implement these best practices, you must use a mobile auditing platform. Such a platform can populate your food safety auditing form with either the FDA Food Code or your own policies. You'll have access at the corporate level to change policies at any time, and these policies are instantly synced across the entire enterprise. Automated forms enable you to increase auditor consistency, track real-time data, perform corrective action, and ensure that each of your locations receives a quality evaluation.

"People have to wear a lot of hats in corporate offices. There simply isn't time to keep track of all the data you need with paper, Excel spreadsheets, or email chains back and forth. There are too many things that fall through the cracks and you waste a lot of time," says Joe Ventimiglia, systems operations services manager, Checkers.

According to managers at Arby's franchisee organization Brumit Restaurant Group, switching to an automated, cloud-based system cut its food safety audit time in half.

9. Demand accountability. When audits are designed and implemented properly, they can help improve a restaurant's performance. But audits must have built-in accountability. When there isn't any accountability, then it's a waste of resources.

That's why restaurants need to ensure there is a corrective action identified for each item on the food safety audit and focus on: first, fixing it for *today* (immediate correction) and second, fixing it for *forever* (long term to prevent repeats).

In conclusion, every restaurant not only needs to regularly conduct food safety audits but also do so using these best practices. A restaurant's reputation is worth protecting and preserving. ■

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What Does it *Really* Take to be a Quality Manger?

Recognizing the career expectations and demands facing today's quality professionals

BY **MICHAEL SPERBER**

First in, last out. These are the general hours of good quality managers. They are hands on, always moving, constantly improving machines who aren't interested in anything but surpassing their own intense quality standards. But what happens when their standards aren't good enough for the customers?

The days of 1,000 page binders of procedure and control are still with us, yet online supplier profiles, online corrective action reports, and online database management are now part of the job. This is all while interfacing with suppliers, certification providers, and customers while preparing for what seems to be the daunting task of yet another audit of some kind. This, in a nutshell is what it takes to be a quality manager in the coming year. Does it ever get easier? No.

In order to supply big box stores, quality managers need to obtain an International Organization for Standardization (ISO) or Global Food Safety Initiative (GFSI) certification, but which one? They need to get certified from a reputable certification body (CB), but which one? Sometimes a specific customer requires a certificate from a specific CB, which yet again forces multiple audits.

Consider the barrage of audits equivalent to a steady stream of guests funneling through your house. It would get a little tiring whether expected or not.

Quality Management Progression Chart

Receiving Inspector → Quality Inspector I → Quality Inspector II → Quality Inspector III → Quality Engineer → Senior Quality Engineer → Quality Manager → Director of Quality

> Without the quality professional, products would crumble.

Today, most quality managers and food safety managers are working with consulting firms while simultaneously improving their internal teams. Continuous improvement for internal auditors and lead auditors doesn't just stop at the latest GFSI or ISO training. It often includes Lean, Six Sigma Yellow, Green, and/or Black Belt certification. Understanding and implementation of Kaizen certification is also necessary, all while running a line which frequently consists of two to three shifts per day, six or seven days a week.

Please keep in mind that these are only the quality needs for outbound business. Internally, a quality manager is responsible for making sure his/her management team understands that the manufacturing product must hold up to stringent standards and pass inspection before being released for sale or further distribution. Often this is met with significant discourse as upper management is receiving concurrent pressure from a board of directors, shareholders, or corporate requirements to hit projected targets. Regardless of projections and pressures from above, it is the responsibility of the quality manager to hold their ground.

So the question to ask now is, why? Why would quality managers want to break into or remain in a role with so many internal and external challenges?

The answer is clear. As a quality professional, it is your responsibility to ensure the safety of the general public. Your standards, in conjunction with local/global standards, help to maintain a level of safety that in a perfect world remains uncompromised. This level of safety is what allows consumers to eat a tortilla

chip without thinking about bacterial disease, to open up a soda/pop without worrying about contents other than the drink within, and to sit at a dinner table without fear of the table itself collapsing. There really is nothing in your life that has not been created, produced, assembled, or consumed without first passing through inspection.

Take great pride in the fact that your job, though at times can feel thankless, is paramount to everything from keeping babies fed through the production of safe infant formula, to keeping your televisions working through the proper production on an assembly line.

Requirements

A degree in food sciences or microbiology is the general course of action to step into the world of food safety. For general manufacturing, an engineering degree is most common. If you want to pursue a more senior position, a Master's degree is generally required or preferred.

Professional certifications run from a Lead Auditor in food to becoming certified in Lean Principles and most importantly Six Sigma in general manufacturing. There are multiple levels of a Six Sigma Certification (Yellow, Green, Black, and Master Black). The difference between a quality manager with an MBA and a quality manager with an MBA and a Six Sigma Black Belt is $10,000 to $15,000 in additional salary per year. Not only does this designation place you in the upper echelon of the quality community but it will make you more desirable to future employers as well.

So why would anybody want to get into the world of quality?

Do you like to give your input and see a positive outcome? Do you like to see things follow a process from start to finish with little to no deviation? If you answered yes then your OCD has led you toward this career. Within the quality ranks, you can build, tinker, engineer, create, and, most importantly, protect product and process from defect and flaw. Once you've conquered your process, and can own it in your sleep, you are ready to graduate from quality manager to quality director (with a minimum experience level of five or more years in a quality manager or equivalent role).

Nearly five to 10 years of climbing through the ranks will eventually lead to a very comfortable and nicely compensated position of quality director (see Quality Management Progression Chart, p. 38). This of course can only happen with a strong work ethic, incredible educational credentials, and a solid work history. A person who has shown movement from organization to organization every one to two years isn't going to achieve the position he/she is looking for through "job hopping."

Recruiting

A suggestion for companies looking to attract top talent: Invest in your process. Tools make the trade and a solid set of tools will attract top talent. Tools aren't as simple as a calculator and a drafting table. I'm talking about people too. The better the people, the better the candidate. You, the executive management team absolutely must, without a shadow of a doubt, support your new quality manager or director. You must be open to change and accept that you are wanting to hire this person because he/she has the necessary skills to improve your organization into the lean and mean machine it needs to be in order to reach the next level.

As a recruiter, I first ask the organization what its hot buttons are within its systems. Based on that answer, I then work with the organization to reevaluate the true needs of the written job description—frequently what is not written is far more important than the generic and obligatory job description.

The responsibility of the quality manager or director is to protect his/her brand as well as the safety of the general public from default or flaw. A qualified individual can start as a college student who is interested in sciences, who then obtains a degree, continues to an entry-level position within a quality department, and matriculates into the most senior quality position within an organization.

A Modern Quality Manager

Today's position of quality manager requires an insanely dynamic person with an internal desire to achieve perfection, who continues to improve, and who has thick enough skin to manage the several dozen audits in a calendar year. Is it worth it? You bet it is because a quality manager is the backbone of an organization. Without the quality professional, products would crumble. Maintaining a quality manager position requires continuous improvement and education to remain an asset for a long and prosperous career. ■

Sperber is managing partner of Quality Resource Partners, an affiliate of MRINetwork specializing in search and recruitment of quality assurance, food safety, sales, and technical professionals within the food and quality sectors. Sperber has more than 10 years of experience in quality management and food safety. Reach him at msperber@qualityresourcepartners.com.

Reducing *Campylobacter* in Poultry: Progress from Across the Pond

Developments in testing and control measures for the U.K.'s leading cause of food poisoning

BY **EZZEDDINE ELMERHEBI**

Campylobacter spp. are the most frequently identified bacterial cause of acute diarrhea in the developed world and can cause post infectious complications such as reactive arthritis and Guillain-Barré syndrome. Reported cases in England and Wales recorded at the Health Protection Agency (now Public Health England, or PHE) have risen from approximately 58,000 in 2000 to about 65,000 in 2012. This has fueled the recent media storm regarding the prevalence of the organism in fresh chickens from supermarkets and butchers. Results as high as 73 percent of chickens testing positive for the presence of *Campylobacter*—according to Food Standards Agency—may come as a shock to many consumers; but for those who work in foodborne zoonoses, like Paul Wigley, PhD, professor at University of Liverpool in U.K., these levels are not a surprise.

"The reality is around one in 100 people get *Campylobacter* infection each year and most of these cases are associated with chicken," comments Prof. Wigley. "The reason why *Campylobacter* has become the main issue in poultry microbiology is widely due to the host; it can colonize the chicken very well—the raised body temperature of birds over mammals and the low oxygen in the gut suit the bacterium well, meaning it can grow to levels of 10^{10} colony-forming unit per gram of intestinal content."

The most frequently isolated *Campylobacter spp.* associated with human disease is *Campylobacter jejuni*, accounting for around 90 percent of cases, followed by *Campylobacter coli*, accounting for many of the remaining cases. Other species are reported (such as *C. lari* and *C. upsaliensis*), but these are rarely associated with human campylobacteriosis cases.

During the 1980s and 1990s, *Salmonella enterica* subspecies *enterica* serotype Enteritidis phage type 4 caused an epidemic that was frequently associated with the consumption of poultry meat and eggs. According to research published in the Journal of Applied Microbiology, the decline of incidence was widely attributed to the extensive vaccination of egg-laying hens against the serovar. Current efforts to reduce incidence of human campylobacteriosis cases largely focus around control strategies, such as hygiene and biosecurity measures of broiler flocks. However, this approach can only be effective if the control strategy efforts are focused throughout the food production chain, commonly referred to as farm to fork strategies. Efforts are underway into the feasibility of a vaccine for *Campylobacter*, however strategies are limited due to an incomplete understanding of the organism's pathogenesis and extensive rate of horizontal gene transfer.

Approaches in Detection

If *Campylobacter* is detected at unacceptable levels within a flock, there is currently not a great deal poultry producers can do pre-slaughter to effectively reduce the levels, especially since there is huge concern regarding the over use of antibiotics that can lead to development of resistance.

A number of post-slaughter controls are being developed, such as freezing, irradiation, steam, or hot water treatment. However, these measures can only be effective if carried out at the right time and no recontamination event occurs.

For food producers the main weapon against *Campylobacter* remains surveillance through testing to properly implement control measures. In Europe the main standard observed for detection and enumeration of *Campylobacter spp.* from poultry is ISO 10272. Originally published

Real-time PCR can be used to amplify and simultaneously detect amplified target by using florescent-labeled probes that generate reporter molecules.

in 2006, it is now currently under revision to incorporate several important changes. The basic format of testing includes selective enrichment in broth followed by selective isolation on solid media with further confirmation of characteristic colonies. One of the most important changes is the description of the detection procedure based on the sample type and purpose of the test.

The standard for detection is split into three groups: A, B, and C. This separation of testing protocols recognizes the challenge of radically different test samples and helps improve the ability to detect *Campylobacter*. All procedures use modified charcoal cefoperazone deoxycholate (mCCD) agar as the isolation medium but differ in the enrichment step.

Detection procedure A is designed for samples with low number and/or stressed *Campylobacter* with a low non-target background microflora, such as cooked or frozen products. Procedure A uses a 1:10 dilution of the sample in Bolton broth, which utilizes a cocktail of cefoperazone, vancomycin, trimethoprim, and amphotericin B to select for *Campylobacter spp*. The sample is incubated at 37 degrees Celsius for four to six hours, followed by a 44-hour incubation at 41.5 degrees Celsius. All incubation is in a microaerobic atmosphere. The lower temperature pre-incubation is to allow for resuscitation of stressed cells prior to the more selective higher temperature. The prolonged 44-hour enrichment is to allow for sufficient multiplication of a low number of target cells.

Procedure B is designed for samples with a low number of *Campylobacter* in the presence of a high level of non-target background microflora, such as raw meat or milk. Procedure B uses a 1:10 dilution of the sample in Preston broth, which utilizes a cocktail of polymyxin B, rifampicin, trimethoprim, and amphotericin B to select for *Campylobacter spp*. The sample is incubated at 41.5 degrees Celsius for 24 hours in a microaerobic atmosphere. The main difference between Bolton and Preston broths is that Bolton is formulated to better cope with the resuscitation of stressed microorganisms, whereas Preston broth is more selective to deal with a high background challenge.

Procedure C does not utilize an enrichment step and is a direct plating method for products with high numbers of *Campylobacter*, such as poultry caecal content. Procedure C can be used with the second part of ISO 10272 concerned with enumeration of *Campylobacter* in the test material.

As previously mentioned, the plating medium of choice in all protocols is mCCD agar, which, unlike both Preston and Bolton broths, is a blood-free medium. In the formulation, blood is replaced by charcoal, ferrous sulfate, and sodium pyruvate to aid in the recovery and growth of *Campylobacter*. The agar is made selective with the addition of the bile salt sodium deoxycholate, the third generation cephalosporin antibiotic cefoperazone and the antifungal amphotericin B.

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Typical colonies of *Campylobacter* on mCCD agar are gray/white, often with a metallic sheen, and are flat and moist. Further confirmation is done by examination of morphology and motility, presence of oxidase, and absence of aerobic growth.

A very similar organism that is often mistaken for *Campylobacter* is *Arcobacter*. Like *Campylobacter*, *Arcobacter* is also a member of the family *Campylobacteraceae* and exhibits a very similar morphology on mCCD agar. A way to differentiate the two, however, is by testing duplicate plates both aerobically and microaerobically. *Arcobacter* can tolerate the aerobic environment and will grow, but *Campylobacter* cannot. The clinical significance of *Arcobacter* is debatable; however, in this case, it is a cause of false positive results and/or incorrect counts.

Preston and Bolton broths have been favored by ISO as the enrichment media of choice, although there are other media that have been shown to be highly effective at selectively enriching *Campylobacter* from other sample types. Exeter broth has been used successfully to enrich *Campylobacter* from samples such as poultry house boot socks used for monitoring levels of the organism in and around the poultry house. Similar to Preston, Exeter uses a nutrient broth base, supplemented with lysed horse blood, but instead uses trimethoprim, rifampicin, polymyxin, cefoperazone, and amphotericin b as selective antibiotics. Again plating is done using mCCD agar, but reduction of background microflora can be achieved with the use of a 0.45-micrometer disk filter. By placing a filter on the agar surface and placing 100 microliters of enriched sample on top, the *Campylobacter* can pass through whilst most other enteric microorganisms are retained. The filter can then be discarded and the plates incubated as normal.

Rapid Methods

Whilst traditional microbiology methods remain at the forefront of *Campylobacter* testing, rapid methods are being further more utilized as a detection tool. ISO guidelines are available regarding the detections of pathogens using polymerase chain reaction (PCR)—ISO 22174:2005 and ISO 20838:2006—and many commercial products are available for *Campylobacter*

that can give a result in around 90 minutes after 24 hour pre-enrichment. Unique DNA targets are amplified to create millions of copies that can be analyzed to give a result. Real-time PCR can be used to amplify and simultaneously detect amplified target by using florescent-labeled probes that generate reporter molecules. These molecules are excited by light and detected by the machine. This process allows for much quicker results without further analysis.

The technology does, however, have its drawbacks. Besides the cost implications, the major issue is the effect of the sample matrices. Many sample matrices, such as water or raw meat, contain interfering inhibitory substances that can reduce or completely prevent the amplification process. It is possible to reduce the effect of such compounds by undergoing a secondary enrichment to dilute out the problem; however this makes the methods somewhat less rapid.

Other technologies exist, such as enzyme-linked immunosorbent assay, or ELISA, and other immunological methods. These methods rely on specific antibodies that capture the target organism, which, in combination with further enzyme chemistry, yields a detectable signal. For this technology to perform, the antibodies utilized must be able to capture all species of interest, which can have highly variable immunological statuses, meaning the antibodies will have variable performance. The detection limit is also lower than that of PCR, but the technology is often cheaper.

Another technology that's gaining greater approval in food and water testing industry is matrix-assisted laser desorption ionization time-of-flight, or MALDI-TOF. Here laser irradiation is used to vaporize a sample (in the form of biomass from an agar plate), releasing charged ions, which are attracted to a detector. The speed at which the ions reach the detector yields a pattern specific to a given organism from a database, thereby giving an identification. Though this technology is proving popular, its reproducibility and reliability is only as good as the library database it is linked to, and the results can be affected by the state of the cell prior to analysis.

Finally, the most exciting technologies to emerge in pathogen testing as a whole are single nucleotide polymorphisms (SNP) analysis and whole genome sequencing (WGS). These technologies, whilst not quite ready for widespread microbiological food testing, represent a giant leap forward in modern microbiology and further progress our understanding of *Campylobacter* and its pathogenesis.

An example of implementation and successful use of WGS is the PHE food pathogen reference laboratory. After several years of development, infrastructure building and protocol validation, PHE successfully implemented WGS of *Salmonella spp.* sent to the reference laboratory. This replaced the lengthy conformation protocol including serotyping and phage typing. A combination of multilocus sequence typing and SNP analysis provide a powerful tool to correctly identify and characterize food pathogens faster and more in depth than able to do before. As well as allowing faster identification and greater ability to source and deal with outbreaks, this technology gives a better understanding of the organism and its source by assessing similarity between genomes. The greatest disadvantage with the technology is, however, the cost and time required to develop a working system for any given organism.

A drawback of all the rapid methods is that, without effective control measures in place to deal with *Campylobacter* once detected, they might not be able to be utilized as well as they could be.

Clearly there is a great deal of work and development ahead for dealing with *Campylobacter*. It is evident from current efforts that there is no single step that will solve the problem. It will mostly like be a collection of efforts from all aspects of the food industry—from production all the way to final product testing—that will prevent the prevalence of *Campylobacter* in poultry. ■

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Pathogens and Meat Mixing: A Field Trial

Adding antimicrobial compounds to the liquid carbon dioxide injection in food mixers has the potential to prevent the replication of pathogens and maintain overall quality

BY **BILL ADAMS, PHD**

The average American consumes nearly 200 pounds of meat each year, all of which is processed in some form or fashion. However, at this time, there is no effective food safety intervention in the meat mixing process. The food mixer has inherent food safety risks as various lots, which have various microbial characteristics, are commonly co-mingled in the mixer. Any pathogen in any one lot will be exposed to that entire batch. The mixer is also one of the last points in meat processing in which an antimicrobial hurdle can be applied.

To meet current food safety regulations, temperature control and pathogenic interventions are required. USDA Food Safety and Inspection Service (FSIS) monitoring and regulation of pathogens is increasingly important through proposed rule changes. Therefore, an intervention for the meat mixing process combining best practices in temperature management and a pathogenic hurdle is warranted.

CO_2 in the Food Industry

One of the most effective utilizations of carbon dioxide (CO_2) in the food processing industry is through bottom injection of liquid CO_2 to chill a variety of meat products. At -109 degrees Fahrenheit, LCO_2 has the refrigeration capacity to chill a batch of meat during normal mixing cycle times, and at the same time, remove heat gained through grinding, conveying, and mixing without adversely affecting protein extraction. During and after mixing, the food purity grade LCO_2 will sublimate out of the mixed meat product leaving no residue. This use of LCO_2 can be the most economic means of chilling the product in a mixer in many regions of the country.

Antimicrobial Compounds

Currently, a number of microbial interventions focus on the use of bacteriostatic compounds used in spray, dip, or rinse form to control the spread of pathogens during processing. The development and acceptance of these compounds is driven by their effective control of pathogens with limited to no quality effects on the food product and manageable costs associated with the process.

The approval of the product at its recommended levels must be accomplished through the USDA FSIS Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products directive as directed by the FDA. Compounds used in food processing are categorized in one of three ways by the FDA: direct food additives, secondary direct food additives, or processing aids.

According to 21 CFR Parts 172 and 173, direct food additives must be identified on the label and provide technical effects to the final food product, while secondary direct food additives are added during manufacturing but are removed from the final food and have no technical effect on the finished product. Processing aids can be added to the food during processing but are either removed or converted into normal food constituents. Processing aids may also serve as functional additives that leave insignificant, nonfunctional residuals in the finished product. A wide variety of antimicrobial compounds are commercially available including acid, chemical, ovo, lacto, bacto, and phyto antimicrobials, each with unique properties that can be used in food processing facilities at a number of intervention locations.

> Surface pH showed a wide range of variability between both control and treated sample averages as well as between compounds used.

The Development of CO_2+

Since CO_2 is a step many processors use in chilling of their product, Air Liquide wanted to incorporate the antimicrobial into the CO_2 stream in order to accomplish both chilling of the product and the benefits of pathogen reduction using the antimicrobial compound. This would help to create an additional intervention and have only one step in the process where both could be accomplished in unison.

Air Liquide developed a proprietary process by which an additive or processing aid can be added to the LCO_2 stream

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Table 1

Antimicrobial Treatment	Log Reduction APC	Log Reduction Enterobacteriaceae
Buffered Sulfuric Acid	1.91	2.37
Peracetic Acid	1.11	1.74
Lactic/Citric Acid	2.04	1.95
Lauric Arginate	0.31	0.17
Citric and Hydrochloric Acid	0.93	1.24
Lauric Arginate x 2	1.96	1.49

Per 800 pound batch

(Continued from p. 43)

prior to injection into the meat mixer. The LCO_2 is used both as a refrigerant and as a dispersing agent for precisely metered antimicrobial compounds. The LCO_2 uniformly chills the product because the mixer uniformly exposes all meat product to the LCO_2, and everywhere the LCO_2 travels, it carries a precise dose of the antimicrobial. This process, known as CO_2+, can also be used to inject a wide range of additives, including preservatives, nutrients, stabilizers, food color, and anti-microbial processing aids.

Technical Evaluation

The combined CO_2+ testing and demonstration unit is a 1,000-pound capacity, skid-mounted, commercial meat mixer that has been integrated with a single control panel into the additive metering system, which can deliver precise amounts of additive to the LCO_2 supply system.

More than 20 commercially available GRAS (generally recognized as safe) antimicrobial compounds were bench tested at Air Liquide's Delaware Research and Technology Center (DRTC) to determine their efficacy on pathogen control. A further challenge test of the top eight performing compounds was conducted at the USDA Agricultural Research Service facility, Wyndmoor, Penn.

At completion of these trials, a preliminary test was conducted at DRTC to determine the carrying and coverage capacity of the CO_2 injection system with the metering pump. The conveying and broadcasting benefits of using the CO_2+ process became visually evident when the antimicrobial and food dye were added to LCO_2 and showed a homogeneous color change throughout the batch. The expansion of the CO_2 allowed complete coverage of the product during the mixing process.

A full-scale field trial was conducted at a poultry processor utilizing seven different antimicrobial compounds. Dosing rates for these compounds were directed by the antimicrobial supplier. The poultry trim product was added to the mixer following aseptic collection of the control samples and dosing time was adjusted in the instrumentation controls after the metering pump was primed with the compound. A six-minute mix time was utilized for each of the 800-pound batches. Upon completion of the mixing, treated samples were collected.

Field Trial Results

All microbial samples were sent to an independent, third-party lab for analysis of aerobic plate count (APC), *Enterobacteriaceae*, and *Salmonella ssp*. Additional samples were collected to study the quality traits, including surface pH, temperature, and color. Due to minimal dosing issues with two of the compounds, these results were unable to be analyzed and ongoing testing is being performed. As seen in Table 1 on page 43, all treatments showed a reduction in microbiological levels. Up to a 2 log reduction was realized in APC and a 2.3 log reduction was realized in *Enterobacteriaceae* with differing compounds. One factor that impacted this series of tests was that the customer had an extremely low incidence of *Salmonella* in the natural control samples that were collected. To that extent, *Salmonella* reduction rates cannot be statistically projected.

Additional control and treated samples were analyzed at the facility's quality lab for temperature, color, and surface pH to correlate any possible relation between surface pH and microbiological results and to determine the effects the treatment had on overall appearance and customer acceptance of the treated product. Results showed a temperature reduction from an average of 40.50 degrees Fahrenheit for control samples to 30.6 degrees Fahrenheit for treated samples (see Table 2).

All treated sample temperatures were consistent (+/-0.3 degrees Fahrenheit). Surface pH showed a wide range of variability between both control and treated sample averages as well as between compounds used. Acid-based compounds showed the largest reduction in surface pH, with the largest reduction seen from 6.29 in control samples to a 3.97 in the treated sample for one compound. Non-acidic compounds showed as little as a 0.7 drop in surface pH between control and treated samples. Color measurements were taken as a means to determine customer acceptability based on color changes between untreated and treated samples. Acid-based compounds increased the L* intensity (L* is the value for the lightness of a color reading; the darkest dark is L* 0 and the brightest light is a reading of L* 100) and decreased a* values to unacceptable levels (the a* value depicts intensity of the red hues in the object; the higher the value, the darker the red color, and lower values indicate lighter red hues); however, non-acid compounds had a much lower effect on these readings.

Table 2

Anti-Microbial Compound	Temperature		Surface pH	
	Control	Treated	Control	Treated
Buffered Sulfuric Acid	39.01	30.57	6.29	3.97
Peracetic Acid	41.21	30.36	5.99	4.71
Lactic/Citric Acid	44.63	30.68	6.03	4.42
Lauric Arginate	41.21	30.86	5.99	5.29
Citric and Hydrochloric Acid	41.16	30.8	6.12	4.55
Lauric Arginate x 2	40.48	30.14	6.07	5.77
CO_2 Control	41.14	30.85	6.08	6.01

Summary

CO_2+ can provide an effective method of reducing bacteria—presumably pathogens—in the meat mixing process. The ability to add an antimicrobial agent as an intervention in the mixer can be a final process before the product is distributed from the processor's facility. Because of its dynamic dispersal capabilities, CO_2 serves as an ideal carrying agent for the compound. Air Liquide is conducting ongoing testing with additional antimicrobial compounds and working with manufacturers to identify dosing levels that allow for appropriate log reduction while limiting the impact on quality and organoleptic traits. ■

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No More Rotten Eggs

The digital thread of food production is redefining transparency to address potential food safety issues | BY KATIE MOORE

We've all seen the headlines: Contaminated peanut butter; metal fragments in cereal; *Salmonella* found in eggs and tomatoes; and melamine in milk. Food safety concerns continue to be at the forefront of public attention, which have led to high-profile product recalls.

While response and communications to recalls are still critical, the primary focus needs to shift toward the prevention of recalls—building safety upfront before products reach consumers. The food manufacturing industry can take advantage of current automation technologies that will put them on the path to true brilliant factory status. Brilliant manufacturing solutions can be used to gather and connect data from every aspect of a production facility and then put into action to continually improve the food production process. This "digital thread" is the seamless flow of data across the product's lifecycle that can be captured, analyzed, and acted on.

Today, manufacturing is being redefined by the digital thread, which promises to increase the power of productivity well beyond what anyone can even imagine. Enabled by the Industrial Internet, today's technology solutions allow companies to connect their equipment and systems to bring together disparate data for increased operational visibility, leverage insights through advanced analytics, and achieve plant optimization for utmost productivity, quality, and sustainability.

According to Grocery Manufacturers Association, the financial impact of more than half of all recalls cost greater than $10 million. In fact, Frost & Sullivan estimates that a total of 76 million food-related illness cases occurred in 2013, with the U.S. spending $40 billion dollars on treatment rather than prevention. Tracking the digital thread from product to manufacturing to services will have a significant positive impact to both food manufacturers and consumers financially. Improving quality and food safety also leads to higher productivity—a critical advantage that's imperative for manufacturers to stay ahead in today's highly competitive environment.

Beyond the obvious financial benefits for food manufacturers who utilize the digital thread, there are other benefits as well, including product quality, safety, production flexibility, meeting compliance, and positive brand reputation.

Product Quality

By gathering data on food production processes, manufacturers can analyze data and identify the best production runs, and then use this "golden batch" as a template for which subsequent production runs should be measured against to ensure the best quality.

Utilizing the digital thread in manufacturing provides greater company control of entire process. Thus, operators can monitor the progress of a batch and control the execution of a recipe, as well as the status of the process from the same supervisory and control environment. The digital thread empowers engineers to quickly and efficiently deploy batch automation, regardless of the underlying equipment—enabling a complete batch solution for small, medium, large, or multi-site applications.

Software that offers rich digital thread traceability capabilities allows companies to trace a product throughout every step of the manufacturing process and identify its exact materials and quality characteristics. It also allows food producers to control the flow of product between equipment and manage in-process inventories in real time with greater transparency between production orders. This optional capability provides manufacturers with the ability to optimize batch production, utilizing time series and historical analysis tools. These results enable consistent reproduction of the "golden batch."

Food Safety

When food contamination happens, it can take a while for manufacturers to root out the cause of the incident. Leveraging software technology, often aided by barcodes or QR codes, manufacturers can track and trace a food product from its sale all the way back through its production process to its raw materials. By following that thread, manufacturers reduce downtime

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by pinpointing the source of contamination and address it so that food production can resume as soon as possible.

Many variables can affect the availability and reliability of data on the plant floor and throughout the supply chain, which can be difficult to track and trace. While most solution vendors apply traceability solely for minimizing the impact of recalls after they occur and aiding customer complaint investigations, manufacturers that instead use traceability data to improve food safety can virtually prevent recalls.

Real-time predictive analytics are vital to help food manufacturers understand what could happen based on trends or if there are parameter changes, providing critical decision support to foresee issues before an event occurs. Advanced software with predictive analytics may leverage robust modeling engines and multivariate analysis to preempt alarm and failure events based on historical models—enabling "active avoidance."

Production Flexibility

Many factors can negatively impact the food production process. For example, if a supplier is late with a delivery of raw materials, it could delay production. Through analytics, manufacturers can determine how the delay will impact production and can quickly make changes to bring in materials from other suppliers or switch production to other products to ensure there is no downtime.

The centerpiece of any good food manufacturing program is standardized operating procedures (SOPs), which ensure that operators consistently adhere to product recipes. Using digital thread enables manufacturers to digitize manual and automated work processes, instead of relying on static paper trails or a binder at an operator station. Addressing the need for better operator guidance, digitization helps manufacturers follow SOPs and work instructions with greater precision and fewer errors.

Analytics also provide an opportunity to correct the problem that is about to occur, which can help prevent quality issues. Take high pH readings in a key processing step, for example, which can compromise product quality; if the pH level starts deviating toward a critical condition, predictive analytics in the digital thread can extrapolate the scenario in real time and determine that a critical condition is likely by using a process model built on past scenarios and process knowledge.

Meeting Compliance

Due to the increasing number of food recalls, regulators are implementing new food and beverage quality standards and requirements to ensure the food entering the supply chain is safe for consumers. The most recent regulation, the Food Safety Modernization Act (FSMA), now provides the FDA with the power to force a food recall and suspend facility operations, as opposed to letting a brand owner make the decision to recall a product.

Besides concerns on FSMA regulations, manufacturers have the added challenge of managing the food quality of global suppliers, third-party manufacturers, and contract packagers. Unfortunately, many companies in this industry are still relying on paper-based records or spreadsheets to document and manage the food supply chain processes and maintain an audit trail. This prevents information to be shared with other facilities in real time and creates inefficiencies in production and change procedures.

Tracking the digital thread throughout the supply chain allows manufacturers to automate quality management processes to meet global compliance requirements and ever-changing regulations. By connecting all related processes, the system increases product safety levels and reduces the costs of overall regulatory compliance.

Positive Brand Reputation

When a product is recalled, a food company shouldn't only be concerned about the effects on its profits, but also the brand's reputation. The power of social media and the 24-hour news cycle allow consumers to hear about a recall faster than ever. Today's companies need to be mindful that news-worthy stories, especially when they negatively affect consumer safety, will spread quickly and make it nearly impossible for companies to react to negative publicity in a timely manner.

One of GE Digital's customers that produces a leading peanut butter brand mentioned that even though the company was not associated with the Peanut Corporation of America, it was "guilty by association" just because it produced a peanut-based product. And as a result, its sales suffered—the whole industry suffered—exemplifying how food safety is everyone's responsibility.

A food recall can affect a brand's reputation for years following the recall. Once a recall has occurred, consumers are less inclined to purchase the affected brand in the future. Remember, it is the consistent adherence to food quality attributes that build brand loyalty. This is why that brand of bread always has that certain softness, or why that potato chip always has the same taste regardless of where you buy it. And that is why manufacturers continue to purchase, or decide not to purchase, ingredients from certain suppliers.

The bottom line is that companies will likely feel the impact of a recall long after the incident is over. By utilizing the digital thread, food manufacturers and suppliers are able to monitor the entire production process and proactively prevent food recalls. You can calculate the loss in sales and profit from a recall—but protecting your company's good reputation is priceless.

Ensuring the Highest Quality

With Industrial Internet-based technology solutions, manufacturers can view real-time production data anytime or anywhere and quickly make adjustments to current production runs. Accurate production data enables companies to identify improvement opportunities and take the right business actions to increase profitability and competitive advantage.

Only by establishing a holistic, integrated strategy, with the right set of software capabilities, can food manufacturers leverage the critical insight, consistency, and transparency needed to identify and address potential food safety issues while products are still within the factory walls. Being able to trace the digital thread of production is critical for tighter real-time controls to help safeguard processes and prevent quality issues. This will ensure batch consistency and food safety, creating easily adaptable product processes, and protecting your organization's brand. ■

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Going By the Book for Track and Trace Success

Technology should possess six traits that allow manufacturers to be more proactive and organized in the event of a product recall | BY **JACK PAYNE**

In the food manufacturing world, fortune favors the prepared. Unfortunately, for many food manufacturers, when it comes to the subject of food safety and issuing recalls, preparation is a missing link in their supply chain.

More educated consumers combined with tougher industry standards are creating a different environment for food manufacturers—one in which they need to take a proactive stance in ensuring their manufacturing process is equipped to deliver the utmost health and safety to the consumers who buy their products.

Similar to Stephen Covey's book, *Seven Habits of Highly Effective People*, which examined the traits displayed by successful people, the following are specific traits exhibited by the track and trace technologies of successful manufacturers.

Trait 1: Provides Real-Time Results and Visibility

When used correctly, track and trace technology should allow manufacturers to identify and address product issues in real time before a product ever leaves the production line. With these insights, manufacturers can correct problems before they ever impact consumers.

Trait 2: Mitigates Risk

Effective track and trace technology can significantly reduce financial risks and save brand reputations. Consider for example the Peanut Corporation of America tragedy. According to reports, it was the deadliest *Salmonella* outbreak in recent years, killing nine and impacting hundreds of others across the country. The outbreak additionally resulted in a virtual life sentence for the company's owner. Implementing the best type of track and trace technology could have prevented the catastrophe caused by contamination. Needless to say, it is well worth the investment and far less costly in the long run.

Trait 3: Accurately and Efficiently Documents Processes

As an example of where effective documentation derived from track and trace technology can come in handy, think of a dairy manufacturer who ships milk to stores throughout the U.S. Some of the stores are mom-and-pop shops while others are large grocery store retailers. An instance occurs where the dairy manufacturer needs to conduct a mass recall of the milk because of a misstep in the production line. In theory, its track and trace technology should document all of the product details from ingredients to distributor/retailer delivery.

Additionally, track and trace solutions can include built-in controls to provide manufacturers with visibility into qualified suppliers and the ability to specify incoming inspection requirements.

Trait 4: Allows Manufacturers to Communicate

One misstep in handling a product or ingredient can result in far-flung serious health problems for consumers. With advanced track and trace technology, manufacturers can better communicate to suppliers and customers if there's an issue. In the event that a recall needs to be issued, the track and trace technology should send out notifications while seamlessly finding the exact origin of the contamination fast.

Trait 5: Enables Preparedness

The more details food manufacturers have, the better. In the event of a recall or near miss, when credibility and time are both of the essence, manufacturers need to be ready to respond to inquiries and take action. Useful track and trace technology can allow manufacturers to answer targeting questions about specific products including: production location, quantity of product, when products were produced, if additional raw ingredients were used, what other products your ingredient was used in, and quality assurance available for each item.

Without having this data easily at their disposal, manufacturers will not be equipped to prevent or quickly respond to contamination.

Trait 6: Keeps Up with Compliance

Realizing the need for increased measures to improve food safety, the FDA Food Safety Modernization Act, or FSMA, was instituted. With this change, focus on current food contamination responses will shift from being responsive to being preventative; an integral place where advanced track and trace technology needs to be implemented.

The FDA has realized the need for reform by placing restrictions in place to make food and beverage manufacturers heed additional regulations before a product reaches the consumer. In thinking of the end customer, the importance behind preparation is more prevalent today than it has been in years past.

The Bottom Line

Overall, too many consumers have fallen ill—or worse—due to foodborne diseases that could have been prevented. Highly effective track and trace technology can not only continue to keep a manufacturer's doors open, but also provide valuable insight into every step of a product's lifecycle that will, if used properly, prevent consumer illness.

When faced with the opportunity to proactively prevent a widespread foodborne illness, save thousands or millions of dollars, and protect your brand, progressive track and trace capabilities inevitably move from the "nice to have" to "must have" technology for any responsible food manufacturer. ■

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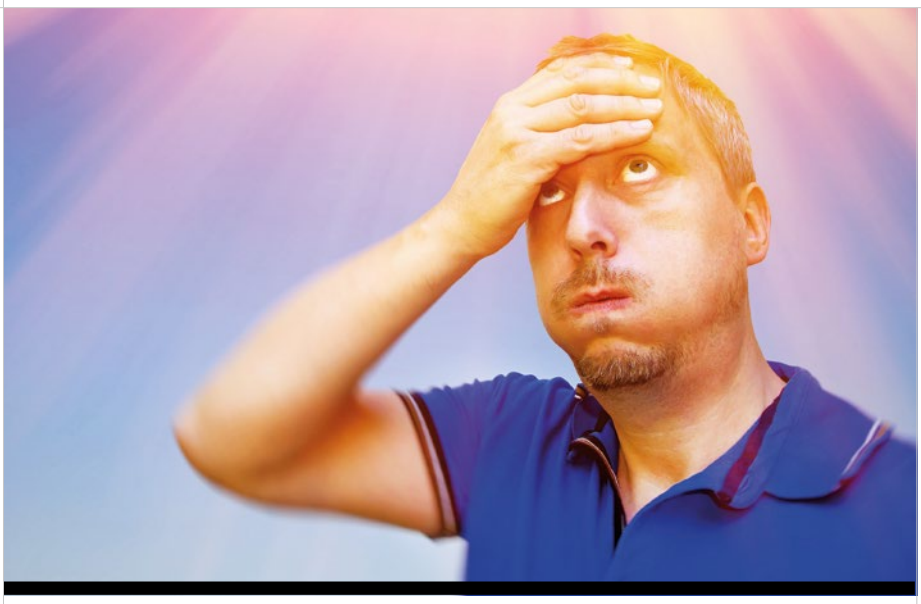
Food Service & Retail

TEMPERATURE MONITORING



Can't Take the Heat?

The latest temperature monitoring technology can help eliminate the stress associated with maintaining temperatures in storage and prep areas

BY **IAN WILCOCK, BSC, PHD, MBA**

While food service providers are charged to take tasty products to market that customers will love, they are tasked to do so with customer safety as their primary ingredient.

Recommended temperatures are often associated with the cooking process, that's only one step for which food service providers must account in the supply chain—consistently maintaining recommended temperatures is equally important in storage and prep areas, for example, to truly maximize safety precautions.

The food industry now has more robust technology and improved temperature-monitoring instruments than ever before to help protect customers from dangerous illnesses. Integrating these resources into a comprehensive safety strategy will help drive higher safety standards, as well as compliance with regulatory and industry regulations. In addition, food service professionals that turn to newer technologies can automate key processes to achieve a variety of business benefits.

Benefiting from the Cloud, Wi-Fi

For fast-paced and high-volume operations, recordkeeping can be particularly challenging. Technology partners to the food service industry, however, have recently introduced user-friendly technologies that help ensure more accurate information is consistently captured and maintained for the future.

Cloud-based technologies, in particular, are increasingly helping food service providers keep records and maintain compliance with higher levels of efficiency, accuracy, and confidence. That's because the cloud enables temperature records to be securely stored in an electronic format and accessed whenever the need arises. And when cloud computing is integrated with wireless temperature monitoring devices, food service providers can take greater control of their safety and compliance strategies.

The Comark Cloud, for example, utilizes Wi-Fi-equipped devices to automate temperature monitoring and recordkeeping across the spectrum of food service operations. Wireless devices are placed in crucial areas—like freezers, coolers, prep stations, and displays—to continuously monitor temperature conditions of the environment, 24 hours a day, seven days a week. When temperatures rise or fall outside of preset safety zones, the system notifies staff of the unsafe conditions via alarm, email, and text message alerts so that proper protocol can be followed to bring the environment back into suitable conditions.

From safety and compliance perspectives, the benefits of this type of automated system are obvious because the technology helps ensure food is maintained in recommended temperature environments to minimize the risk of illness.

Wireless and cloud-based systems can bring about even greater advantages from business and operational standpoints. They can prevent large amounts of temperature-sensitive inventories from being spoiled—and written off as a financial loss to the company—when freezing, cooling, or heating systems unexpectedly go awry or completely fail.

Handheld Safety

The newest generation of handheld temperature-monitoring devices is also bolstering food safety protocols and compliance strategies. By integrating smart technologies into these instruments—and synching them with easy-to-use software—these handheld instruments provide value and capture robust data that is crucial to regulatory and governing bodies.

For instance, Comark recently developed the handheld HACCP Touch to

drive greater efficiencies in temperature collection and help ensure key compliance-related tasks are quickly designated to their proper channels—and that any action related to those tasks is recorded for future reference. Using handhelds like these, product temperatures are recorded at critical moments during the life of a food product, including at receiving, storage, preparation, cooking, and handling.

Corrective-action commands can also be programmed, which gives rapid guidance to staff when it determines a temperature has fallen outside of a specified range. This capability empowers a user to quickly take approved—and compliant—steps when a situation requires it.

The new handheld generation is also designed for volume, capable of recording up to 65,000 temperature readings.

Waterproofing and Antimicrobial Agents

Not to be outdone by data loggers and recorders, measurement devices are also innovating by utilizing waterproofing solutions and antimicrobial agents to add an important second line of defense to support existing hygiene procedures.

Waterproof exteriors serve as pseudo force field to the temperature probe while antimicrobial agents added to the instrument's plastic coating support bacteria breakdown—stopping their reproduction, therefore inhibiting growth, and ultimately reducing the risk of spreading harmful microorganisms.

These two coating advances provide additional peace of mind in knowing the instruments and probes themselves are contributing to the fight against harmful bacteria and other microorganisms.

All About Automation

What comes next in the life of temperature monitoring? The answer is automation—actually, automation is already here, and it's changing the game for the food service industry.

The introduction of cloud computing, Wi-Fi-enabled, and software components help automate many tasks that are currently performed manually.

Instead of relying on staff members to check temperatures at assigned timeframes, smarter systems that continuously monitor and record temperatures—and those that capture records digitally instead of in paper logs—bolster consistency and accuracy.

Records can be pulled in real time via computer or even smartphone from a user-friendly dashboard. Historical records can also be pulled from a secure digital archive.

In recent years, temperature monitoring has relied largely on people. As with any manual task, human error can affect data consistency, quality, and accuracy of that work, and in the case of monitoring, result in inadequate or unsafe conditions.

With wireless and paperless temperature monitoring solutions, however, automation drastically reduces the chances for human error to occur. In addition to more accurate records, an automated system allows for constant monitoring, expectations that are far too time-consuming and costly to expect of a manual monitor.

Facilities are also able to be alerted to the slightest fluctuation in temperature, an essential component to reducing the risk of compromised products and spoilage. Digitally archived reports are easy to reference and track over time. They also create an audit trail should any regulatory questions arise. Facility managers can find peace of mind knowing temperatures are safely and accurately aligned with regulatory standards, and executives can focus their attention on other areas of the business, like sales, innovation, and manufacturing.

Food safety is highly dependent upon safe temperatures, which is why it's crucial to ensure temperature monitoring from the supply chain to the customer is accurate and consistent. As temperature monitoring technology diversifies and becomes more accessible—and more widely utilized—across the industry, foodborne illnesses and regulatory concerns can be reduced drastically. But food service providers must be sure they are partnering with credible resources that understand the multidisciplinary approach required to achieving safety standards and compliance requirements. ■

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NEW PRODUCTS

Compact X-ray System

The X5c (compact) model is aimed at food manufacturers, processors, and packers running multi-product, retail ready lines that are keen to make the switch to X-ray technology for the first time or as end of the line product quality checker. It has multilevel password protection for improved data management, which means the system can log events against individual operators. Brushed 304 stainless steel offers an hygienic design for low maintenance and serviceability. A quick release belt can be completely removed without the need for tools or the belt tension can be eased for cleaning. The sloping surfaces prevent food particles and water droplets accumulating in crevices thus reducing drying time. Ideal for detecting glass, calcified bone, dense plastic, rubber, stone, as well as ferrous, non-ferrous, and stainless steel metals in various packaging. The X5c operates at line speeds up to 164 ft./min. and measures 3.3 ft. in length. It's capable of handling products up to 3.94 in. in height and 11.8 in. in width and weighing no more than 6.6 lbs. **Loma Systems, 800-872-5662, www.loma.com.**

High Resolution Mass Spec System

The X-Series mass spectrometry (MS) platform, which includes SCIEX OS software, is comprised of customized models, each fully-loaded with user-friendly software, methods, and libraries custom-designed for targeted customer applications. The first model, the X500R, was designed exclusively for routine food, environmental, and forensic testing labs. Data acquisition capabilities have been extended to include SWATH Acquisition, MRM acquisition, information dependent high-resolution MS acquisition (IDA), and high speed MS/MS scanning. **SCIEX, 877-740-2129, www.sciex.com.**

Instant Read Thermometer

The Thermapen Mk4 provides full readings in only 2 to 3 seconds. Users can hold it in any direction and the display automatically rotates right side up so users can read it in any position. The Mk4 knows when it's dark and turns on the backlight, making it easy to read at dusk or in complete darkness with maximum battery life. Or users can simply touch the sensor window anytime with finger and the display lights up. Leave the probe open and the Mk4 stays on while in use. Set it down, and Sleep Mode saves battery power. Waterproof to IP67. **ThermoWorks, 801-756-7705, www.thermoworks.com.**

Salmonella Testing

The 3M Molecular Detection Assay 2—*Salmonella* features proprietary 3M nanotechnology. A single assay protocol enables batch processing of samples and improves efficiency in the laboratory. Incorporation of a color-change indicator provides increased confidence during the process. According to company, compared to first generation tests, assay processing time is 30% faster and instrument run time is only one hour. Short enrichment times are as low as 10 hours for 25 gram or composited 325 gram raw meat samples. **3M Food Safety, 800-328-1671, www.3M.com/foodsafety.**

Media Preparation System

Demeter is designed to streamline the media preparation process in commercial food testing labs. It automates the traditionally manual, dehydrated media reagent preparation step in labs for increased testing throughput and accuracy. The system records the volumetric amounts and temperatures (NIST traceable) used in a test then feeds that information into a laboratory information management system, streamlining record-keeping for regulatory compliance. Demeter has a printer that produces a label for pasting into lab notebooks, and a flash drive for recording the most recent test results, with nonvolatile storage as a backup. The system is also self-sterilizing. It's suited for the media preparation and testing of a variety of pathogens, including *E. coli, Listeria*, and *Salmonella*. **Heateflex Corp., 626-599-8566, www.heateflex.com.**

In Other Product News

Linde Gases, a division of The Linde Group, announces that BOC, Linde's U.K. and Ireland subsidiary, is a primary collaboration partner in The Advanced Cooking and Cooling Technology project, a two-year venture to develop an innovative cooking and cooling system to dramatically improve quality and healthiness of ready meals. Project seeks to combine two food manufacturing processes: steam infusion technology for rapid cooking and rapid cooling using liquid nitrogen.

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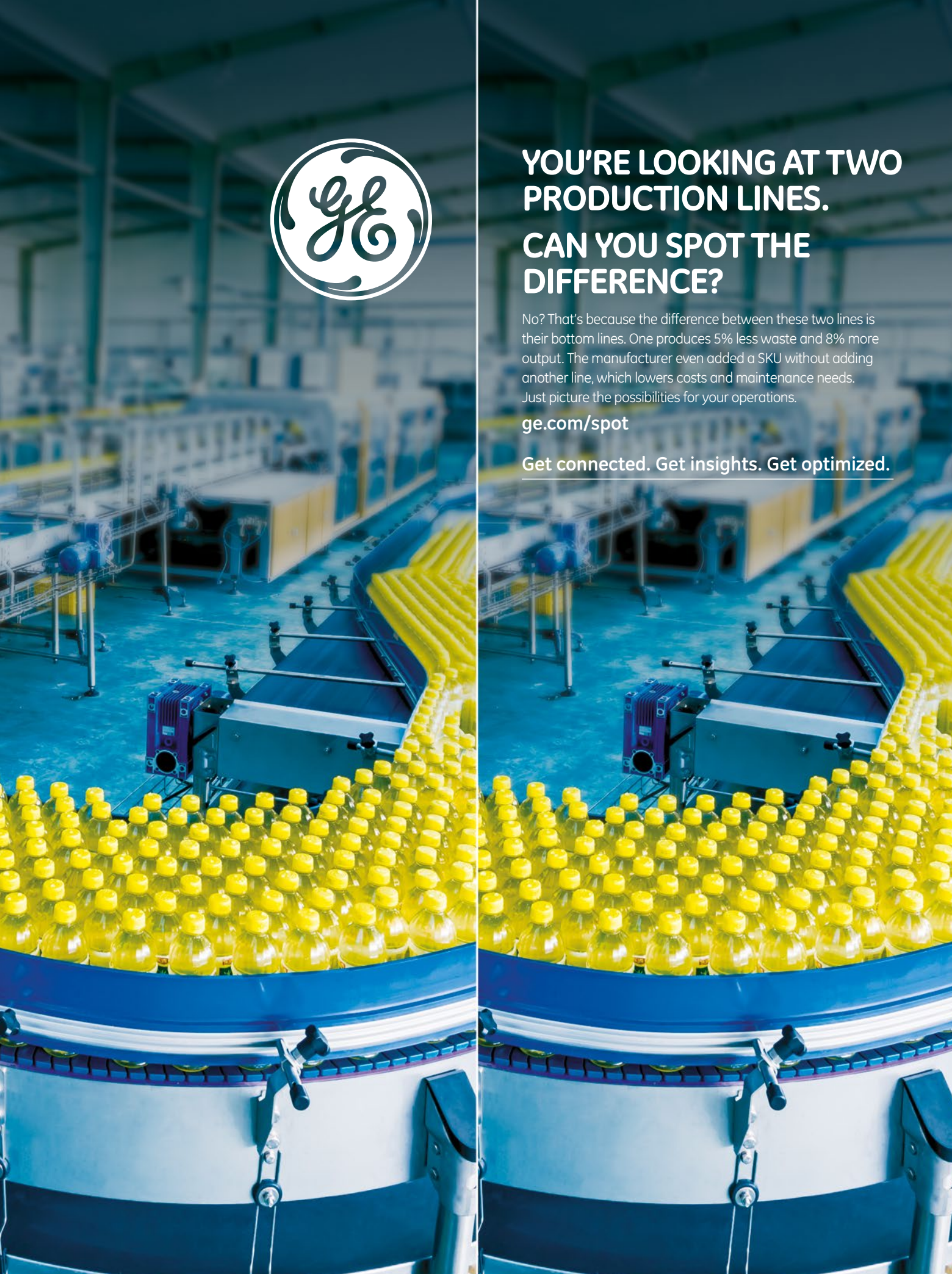

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