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Volume 22 Number 4
AUGUST/SEPTEMBER 2015

Food Quality & Safety

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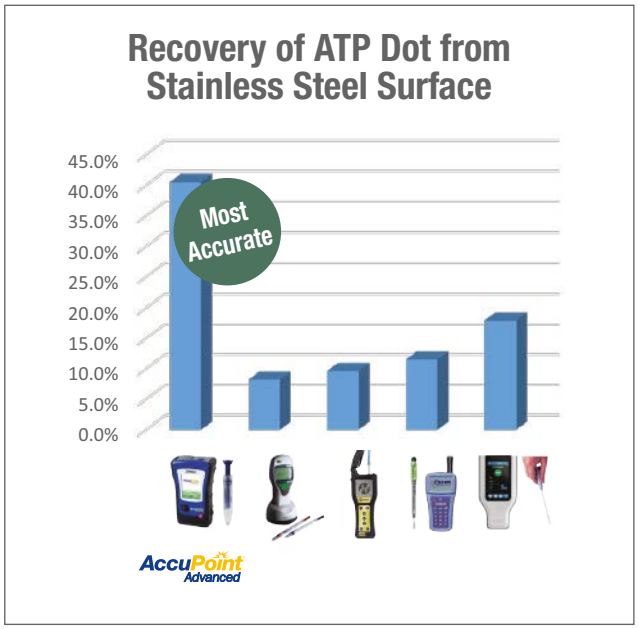

Source: Sanitation Sampler Assay protocol – Real World Study, July 13, 2015. Applied Research Center at NSF International. For a copy of the study please contact Neogen.

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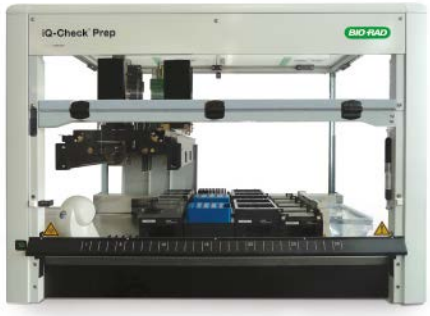

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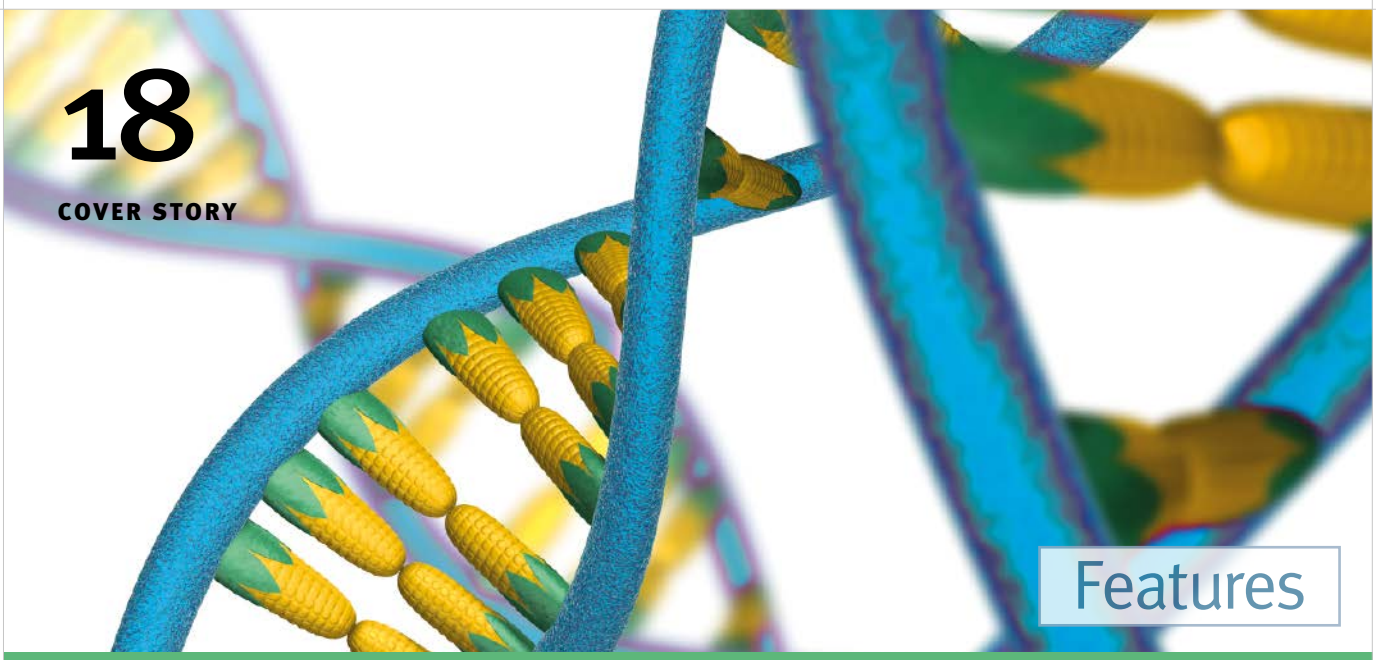

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To read this article, go to the current August/September 2015 issue on www.foodqualityandsafety.com:

- High Pressure Processing in Food Product Development

CORRECTION

In the "Asia's Forging Ahead with Big Steps and Little Steps" article for the print June/July 2015 *Food Quality & Safety* issue, the information pertaining to Shanghai Husi Food Co., a subsidiary of OSI, on pages 17 and 18 was not adequately fact checked and therefore the magazine is retracting the statements pertaining to company.

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From The Editor

The U.S. FDA took steps in June to remove artificial trans fats from processed foods. After its review of the scientific evidence, the agency declared that partially hydrogenated oils (PHOs), the primary dietary source of artificial trans fats, are not "generally recognized as safe" (known as "GRAS") for use in food.

Georges Benjamin, MD, executive director, American Public Health Association, agrees there are no safe levels of trans fat. "By FDA's estimation, partially hydrogenated oils cause up to 7,000 deaths each year in the U.S. and should be phased out of the food supply as soon as possible," he says. "FDA has also concluded that the economic benefits of eliminating the use of partially hydrogenated oil greatly outweigh the costs of switching to healthier oils."

Although our publication doesn't necessarily focus on public health issues of the food industry, FDA's latest move will nonetheless impact our readers on how they manufacture their products.

The agency has set a compliance period of three years to allow food manufacturers to either reformulate products without PHOs and/or petition the FDA to permit specific uses of PHOs.

As manufacturers begin to explore ways to eliminate trans fats from their products, there is concern that many will turn to palm oil, which some experts believe isn't any better for people's health because it's high in saturated fats. In addition, while palm oil is a cheap option, the majority used in America's food supply is produced in ways that cause deforestation and human rights abuses in developing countries.

"It's heartening that the FDA has banned trans fats for the health of U.S. consumers, but we must ensure this move does not create the perverse consequences of rain forest destruction and land grabbing in poor countries," points out Jeff Conant, international forests campaigner, Friends of the Earth.

The American Soybean Association (ASA) believes it may have a better alternative. According to the organization, the U.S. soybean industry plans to ramp up production of high oleic soybean oil that can safely replace PHOs and palm oil in many food applications.

"Soybean oil contains no trans fat, is low in saturated fat, is sustainable, and is a broadly available, domestic option for the food industry here in the U.S.," comments Wade Cowan, ASA's president and a soybean farmer. The organization will use FDA's compliance time period to get the high oleic trait integrated into soybean varieties as well as approved in overseas markets so as to be able to meet the future needs of the food industry.

Marian Zboraj
Editor

Food Quality & Safety
FARM TO FORK SAFETY

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NEWS & NOTES

Controlling *Listeria*

The FSIS' updated "Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens" discusses steps that retailers can take to prevent certain ready-to-eat foods that are prepared or sliced in retail delis, such as deli meats and deli salads, from becoming contaminated with *Lm* and thus a source of listeriosis. FSIS has included information from the FDA Food Code, scientific literature, other guidance documents, and lessons learned from FSIS verification sampling and review of sanitation programs for *Lm* in meat and poultry processing establishments.

Bolstering Small Agribusinesses' Competitiveness

GFSI and the International Trade Centre's (ITC) free public customized joint online application of the Global Markets Programme is designed to bolster the competitiveness of small- and medium-sized agribusinesses, enabling them to better access global markets and contribute to food safety. The tool serves as a first entry point for food manufacturers to learn and adhere to best food safety practices, generate diagnostic profiles directly online, and be able to share those with business partners and auditing organizations. It provides a real-time snapshot of their current arrangements against the requirements of the Global Markets Programme. Smaller business owners can also look at other standards for sustainability and food safety within the ITC Standards Map.

States Vary Widely on Reporting Outbreaks

U.S. states vary widely in how well they detect, investigate, and report outbreaks of foodborne illness, according to a new 50-state analysis from the nonprofit Center for Science in the Public Interest (CSPI) entitled "All Over the Map: A 10-Year Review of State Outbreak Reporting." States are also reporting fewer outbreaks to the CDC. From 2009 to 2012, the average number of reported foodborne outbreaks decreased by about one-third compared to the six preceding years. CSPI found widely different outbreak reporting rates even among adjacent states with similar populations. Florida, for instance, reported five times the number of outbreaks as Alabama when controlled for population, and Maryland reported four times the number of outbreaks as West Virginia. A high outbreak reporting rate actually can prevent illnesses, as it indicates state and local public health officials are looking for outbreaks and are more likely to identify contaminated foods or offending restaurants.

Anti-Counterfeit Packaging Expected to Reach $62.5 Billion

A new report by Allied Market Research, titled "Global Anti-Counterfeit Food & Beverage Packaging Market—Industry Analysis, Size, Growth, Trends, Opportunities, and Forecast, 2014-2020," forecasts the market to grow at a CAGR of 16.1% during 2015 to 2020. Holograms segment would be the leading position in overall authentication technology market through to 2020. RFID technology exhibits fastest growth at 20.4% CAGR. The report finds that in 2014, overt holograms held about two-third revenue share in the overall hologram authentication technologies market. It also finds that consumers continue to prefer paper barcode over polyester barcodes. North America is predicted to continue to lead the global market due to higher adoption rate and affordability for novel traceable technologies, followed by Europe. Asia-Pacific is projected to be the fastest growing region at an estimated CAGR of 18.1%.

Calorie Counts on Menus Get Pushed Backed

The U.S. FDA is extending deadline for chain restaurants to disclose calorie counts on menus by a year to the end of 2016, according to Reuters Health Medical News. FDA set a national standard for restaurant chains with 20 or more outlets late in 2014 to make people more aware of the risks of obesity posed by fatty and sugary foods as part of the Affordable Care Act. The calorie rule covers meals at sit-down restaurants, take-out food, bakery items, ice cream from an ice-cream store, and pizza, which will be labeled by the slice and whole pie. The rule also includes movie theaters, amusement parks, and alcoholic beverages served in restaurants, but not drinks mixed or served at a bar. FDA plans to issue in August a draft guidance to answer frequently asked questions the agency has received to assist establishments in complying with the rule.

Business Briefs

Agilent Technologies Inc. and **Waters Corp.** formalize agreement to exchange instrument controls to improve the productivity of customers who own software and instruments from both companies.

Law firm **Arent Fox LLP** forms a new alcohol beverage industry group that is composed of more than 20 attorneys spanning the firm's four offices that provide corporate, litigation, and regulatory counsel.

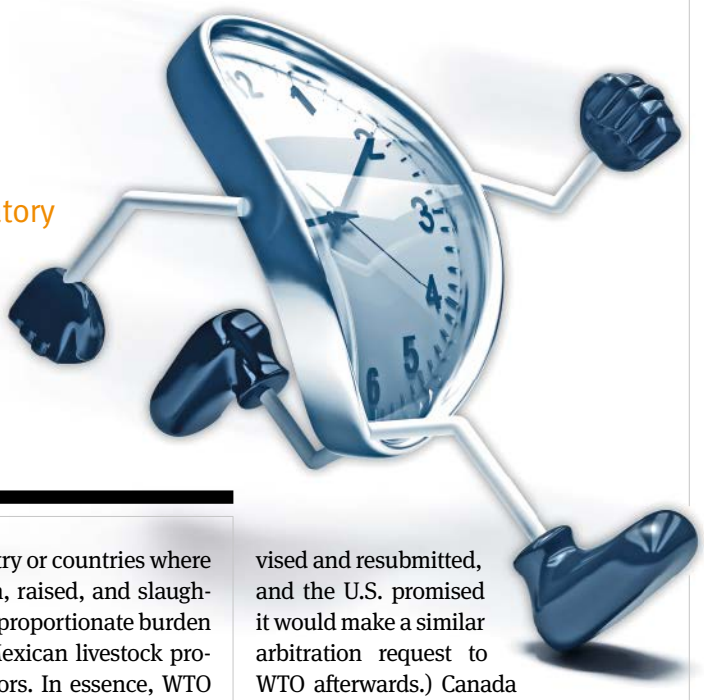
Neogen Corp. acquires the assets of **Sterling Test House,** a commercial food-testing lab based in southwest India, which will serve as a base for the company's new operations in the country.

Washington Report

COOL Running Out Of Time?

As Canada and Mexico prepare to impose retaliatory tariffs on U.S. exports, many question whether COOL is truly a food safety issue and wonder why other countries have mandatory COOL requirements without facing any dispute

BY **TED AGRES**



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Attention is shifting to the Senate at press time as the last best hope for averting a potential estimated $3.7 billion in annual retaliatory tariffs against the U.S. imposed by Canada and Mexico. While the final monetary amount remains to be determined, tariffs have been authorized by the World Trade Organization (WTO) in response to U.S. mandatory country-of-origin labeling (COOL) requirements on retail sales of fresh beef and pork.

In June, the House of Representatives voted to repeal provisions of the U.S. COOL law by a vote of 300-131. The bill (HR 2393), removes COOL labeling requirements not only for beef and pork but also for ground beef and poultry, even though the original complaint did not involve chicken and WTO has ruled that origin labeling for ground beef was permissible. The Senate Agriculture Committee held a hearing on COOL in June but has not taken further action. Whether there are enough votes to pass repeal legislation in the Senate is doubtful, and sentiment seems to favor making COOL provisions voluntary. But unless legislation is enacted soon, the door remains open for retaliatory measures to be imposed as early as summer's end.

In May, the WTO ruled for the fourth time in as many years that the U.S. COOL law, which requires retail label information specifying the country or countries where an animal was born, raised, and slaughtered, imposes a disproportionate burden on Canadian and Mexican livestock producers and processors. In essence, WTO said that COOL was discriminatory because live cattle and hogs imported from those countries must be segregated from U.S. herds, adding to production costs.

Canada is seeking more than $3 billion in annual compensatory tariffs and Mexico is seeking more than $653 million. Canada has indicated it would impose hefty import fees on a broad array of U.S.-made products. Previously issued lists included items from seemingly every state, including beef, soybeans, chocolate, ketchup, frozen orange juice, wine, apples, cherries, and even manufactured goods such as stainless steel pipes, chairs, and even mattresses. A complete list including tariffs from Canada is said to be forthcoming. Mexico has yet to finalize its list, "but we expect it to be just as damaging," says Senate Agriculture Committee chairman Pat Roberts (R-KS). "The U.S. economy cannot tolerate such economic injury."

In June, WTO agreed to a U.S. request for it to arbitrate Canada's monetary claim based on the U.S. contention that the analysis of economic damages was flawed and excessive. (Mexico's retaliation request contained technical errors and was to be revised and resubmitted, and the U.S. promised it would make a similar arbitration request to WTO afterwards.) Canada dismissed the U.S. arbitration request as a delaying tactic.

"In all previous rulings, the WTO has found Canada's economic analysis regarding COOL to be robust," said Gerry Ritz and Ed Fast, Canada's ministers of agriculture and international trade, respectively. "The only way for the United States to avoid billions in retaliation by late summer is to ensure legislation repealing COOL passes the Senate and is signed by the President," they said in a joint statement. WTO's ruling regarding the economic value of the tariffs is expected by summer's end.

COOL and Food Safety

Often overshadowed in the debate over high-stakes tariffs and trade retaliation is the extent to which COOL's labeling requirement actually supports food safety or enhances consumer choice. Those supporting the law's repeal, including some meat producers, ranchers, produce groups, and others, claim COOL was never intended to foster food safety.

"Everyone knows this is not about food safety. It's an issue of marketing, and that

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should be decided in the marketplace," says Barry Carpenter, president and CEO, North American Meat Institute. "We hope the Senate will move quickly to vote for repeal so the president can sign the bill and put this failed experiment behind us."

"Mandatory food labeling is not about food safety," said Rep. Dan Benishek (R-MI) during floor debate in the House in June. "No matter where our food comes from, regulations remain in place to ensure safety and traceability regardless of origin."

The COOL Reform Coalition, an umbrella group of more than 100 associations and companies supporting repeal, said "it is grave and disheartening that the federal government has risked a serious self-inflicted wound to the American economy over a meat labeling rule that has nothing to do with food safety."

But Jaydee Hanson, senior policy analyst at the Center for Food Safety, says, "knowing where food came from helps speed the process of tracing the source of a food issue," such as *E. coli*.

Long-time food safety advocate Rep. Rosa DeLauro (D-CT), said the House's decision to repeal COOL flies in the face of free markets and consumer choice. "People deserve to know where their food comes from," DeLauro said during House debate. "American farmers and ranchers deserve the opportunity to distinguish their products. It is an economic truism that complete and accurate information is one of the cornerstones of a free market."

A 2013 survey conducted by the Consumer Federation of America found that 90 percent of Americans favored a mandatory country of origin labeling on fresh meat. "If Congress repeals COOL, then the next time consumers go shopping for a steak or chicken for their families, they won't be able to tell where that product came from," says Chris Waldrop, director of the federation's Food Policy Institute. "That's completely unacceptable. Consumers want more information about their food, not less." Citing the survey, Rep. Jim McGovern (D-MA) says the House's rush to repeal COOL amounted to, "We don't really care what the American people want. We're just going to cave."

The COOL provisions are included in farm bills passed in 2002 and 2008 and were enacted in 2009. A congressionally mandated economic analysis produced for USDA in April 2015 concluded there was "no measureable benefit" to consumers from mandatory COOL requirements. The report, prepared by agricultural economists from Kansas State University and the University of Missouri, concluded that "measurable economic benefits from mandatory COOL would be small." In addition, they also found "little evidence that consumers would be likely to increase their purchases of food items bearing U.S.-origin labels."

"While the economic benefits of COOL may not translate into measurable increases in market-level consumer demand, USDA's regulatory impact analyses and numerous comments received on the regulatory proposals indicate substantial interest in COOL," the report stated. "A consumer's right to know benefits those consumers who desire COOL information."

The Senate must take action on COOL before Canada and Mexico impose retaliatory tariffs, says Roberts. He had hoped the Senate Agriculture Committee would hold markup hearings on a repeal bill before Congress adjourned for summer recess in August.

Ranking committee member Sen. Debbie Stabenow (D-MI) in June introduced a draft proposal that would repeal mandatory labeling for beef and pork and allow voluntary labeling for meat products exclusively of U.S. origin. While some lawmakers saw promise in the compromise, others did not. "Making COOL labels voluntary does not automatically eliminate trade disputes," says Food & Water Watch executive director Wenonah Hauter. "Voluntary COOL is indistinguishable from total repeal," she added. "Meatpackers won't use it, consumers won't see it, and U.S. farmers and ranchers won't benefit from it."

European, Australian COOL

In her comments on the House floor, DeLauro noted that more than 60 other countries require mandatory labeling. COOL for beef has been required by several European countries for nearly a decade. The European Commission enacted a new rule effective April 1, 2015 that all packaged, unprocessed fresh, chilled, and frozen swine, sheep, goats, and poultry must carry labels requiring "the place of rearing and the place of slaughter."

"Today's consumers...increasingly want clearer and more understandable food labeling to help them make informed choices on the food they eat," the European Commission said in an explanatory memo. "Those rules intend to protect consumers from misleading origin indications and will ensure a level playing field between food business operators."

Australia is considering similar labeling requirements, even though it was a signatory to Canada's and Mexico's WTO complaint. "For too long people have been talking about country of origin food labelling, and nothing much has changed," said Prime Minister Tony Abbott in February, following an outbreak of Hepatitis A from frozen berries imported from China. "Whenever we have a problem with imported food in particular, people want to know more about where their food's coming from," Abbott said. "It's important that we grasp this particular nettle and actually make a difference."

Why no one seems to be complaining about the European Union's (EU) and Australia's labeling efforts or why Canada and Mexico did not complain about U.S. fish or poultry is not easily answered. "Perhaps the recordkeeping/verification requirements of the U.S. are more burdensome that those of the EU, or Canada and Mexico simply don't see the EU as being as much of a threat as the U.S.," speculated David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods, in an online post. "Perhaps it is simply lobbying and politics?"

Regardless, Dr. Acheson doesn't see COOL as being primarily a food safety issue because of the level of control that USDA's Food Safety and Inspection Service already has over imported meat and poultry, as compared to the controls FDA will have over other imported foods under the Food Safety Modernization Act once those rules are finalized. "From my perspective, I want to see food companies spend money on controlling real food safety risks based on priority—not on areas where risks are minimal to none. The public and private sectors only have limited food safety resources, so let's not squander them on areas of very little return," Dr. Acheson said. ■

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

Industry Insights

The Shifting Definition of Food Security

The concept of a second Green Revolution consists of a transition from food security to also providing safe and nutritious food

BY **PAUL B. YOUNG, PHD**

The way we define food security is changing.

For decades, food security was viewed exclusively through the lens of shortages. In the 1960s, when daily food availability in emerging countries was just 1,850 kilocalorie (kcal) per person and as many as half of the world's population were malnourished it is easy to understand our narrow focus on increasing food production. The challenges we face are now shifting.

Food scarcity remains a critical issue but the Green Revolution, which featured a series of transformational agricultural innovations, dramatically decreased its scale. The development and distribution of high-yielding grains, pesticides, and herbicides, and innovations around crop management were just a few of the transformational changes that are credited with saving millions of people from starvation.

By 2008, the daily food availability in emerging nations grew to 2,640 kcal per person and today roughly one in 10 people in the world don't have enough to eat. Food production has increased an estimated 300 percent in the last half century as a result of new technologies that enable farmers to be more productive with their land.

As food scarcity diminishes, we have the luxury, and the responsibility, to consider a broader definition of food security that incorporates the significance of safety. The rapid growth in food production continues to outpace the spread of agricultural practices and safety processes that protect the integrity of crops and livestock. For instance, a number of the pesticides and herbicides that are now ubiquitous have environmental and health consequences we need to examine, and the explosion of crop production in developing nations has made safety regulations more difficult to set and enforce.

We are quickly finding the same technologies that transformed the global food supply are threatening to damage it.

The challenges of growing supply chains, increased commodities exchanges, and surges in cross-border trade have revealed our system is not fully prepared to ensure food safety around the world. Our once relatively centralized agricultural infrastructure has given way to an environment that features expanded trade with and between developing nations, which presents new opportunities for unsafe products to enter global markets.

A Second Green Revolution

It is time for a sequel to the Green Revolution that takes into account our evolving understanding of how to ensure the quality, traceability, and safety of our food in light of an increasingly complex and geographically diverse supply chain. We all share the obligation to address these issues. Unsafe food practices in one country can, and often do, harm companies and consumers in another.

The second revolution must entail a globalized approach to food safety—a concerted effort to harmonize food safety in every region by leveraging the full sum of our technical knowledge to create standards, training, and testing procedures that ensure our global food system is consistently safe and sustainable.

This vast challenge can only be solved through a collaborative approach that incorporates the perspectives and experiences of every stakeholder in the food space. The food industry, its suppliers and providers, governments, and non-government organizations (NGOs) all have an important part to play in creating a food system that is responsive and evolves with our growing needs in the decades to come.

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At the center of the global food system, the food industry can be a particularly active member in part two of the Green Revolution. The industry has valuable experience from its extensive efforts to develop safer products for its consumers, and its strong influence across supply chains can be used to share best practices, change behaviors, and conduct quality assessments that reach back to primary producers.

But the food industry is not just limited to companies that produce food. Service and technology solution providers must also have a significant role in advancing food safety and security.

After all, effective, uniform, and transferrable testing methodologies lie at the crux of a global solution for enhancing food safety. It also has a critical role in ensuring standards harmonization, enforcing accountability, and demonstrating compliance. And recent innovations in testing technology have greatly increased the simplicity, sensitivity, reproducibility, and versatility of testing systems, which means they are well-equipped to meet rising regulatory demands.

Tests must also be easy to deploy so that they can be incorporated into the process of food production, trade, and commodities exchanges without being overly burdensome. This is an area in which Waters Corp. has been particularly successful. One recently developed testing method requires just two minutes to identify melamine in baby formula—which was the culprit in China's infamous milk scandal that killed six infants and hospitalized more than 50,000 others.

Governments' role in the new Green Revolution is equally if not more important. Government agencies are responsible for simultaneously seeking to protect citizens and market access by ensuring that inbound and outbound foods are compliant in equal measure. The global integration of the food supply chain forces us to rely on health and food safety agencies in all parts of the world to be good stewards of the public's trust. Strong regional leadership is critical to fostering compliance and enforcing accountability. And to supplement government regulation, non-governmental organizations can promote food safety compliance while being active participants in facilitating knowledge transfer to emerging economies.

The Power of Partnership

If each stakeholder group does their part individually, we will make great strides in building a secure and sustainable food system. But real progress requires public-private partnerships that bring these groups together around shared goals. While partnerships on the scale necessary to affect our global food system are inherently difficult to establish and manage, there are real-world examples that such ambitious collaborative efforts can be successful.

The Global Food Safety Partnership (GFSP) is among the most promising efforts in this area. Growing out of a joint initiative by the World Bank and the Asia-Pacific Economic Cooperation Food Safety Cooperation Forum, the GFSP, aims to leverage and coordinate the collective activities of governments, inter-governmental bodies—including the Food and Agriculture Organization of the United Nations and the United Nations Industrial Development Organization—as well as industry and NGOs. Private companies, such as Nestle and Waters, provide valuable technical insight.

In its first four years, the GFSP has already supported a number of capacity building activities in a range of countries, including most recently a comprehensive and scalable "train the trainer" program in China. The initiative has created new experts in Chinese governmental agencies and supported them as they begin to roll out the training programs to their respective organizations. Future initiatives include a needs assessment being conducted in Zambia and an aquaculture practices training program in Malaysia. The partnership is also developing a long-term strategy to collectively support and sustain investment in food safety systems.

The International Food Safety Training Laboratory (IFSTL), which operates out of the U.S. FDA supported Joint Institute for Food Safety and Applied Nutrition at the University of Maryland, is dedicated to training in the area of chemical and microbial food safety. In partnership with GFSP, the goal of the IFSTL is to deliver training that is, ultimately, locally based (more directly situated at the point of need), has a global platform for delivery, harmonized to standards, and delivered by worldwide experts. To this end, the GFSP recently launched a pilot training program in China to expand the footprint of locally based training. This pilot involved a train the trainer program for Chinese government scientists at IFSTL in Maryland, followed by IFSTL instructors supporting these fledgling trainers as they in turn delivered the training in China to scientists from their organizations. The program funding came from both public (USDA) and private (Waters, Nestle, Mars Inc.) sources, with additional funding from GFSP directly. The efficacy of the training and its implementation will be evaluated through Food Analysis Performance Assessment Scheme proficiency testing samples donated by the Food & Environment Research Agency in the U.K., an IFSTL network affiliate.

In many respects, IFTSL represents how the key elements required for the next Green Revolution can fit together. The partnership benefits from private sector funding, equipment contributions, along with expertise and experience from academia and government agencies.

Share the Work, Share the Rewards

By working closely with primary producers, food companies can provide education that improves the quality of products generally available while increasing the reliability and safety of raw ingredients. For companies like Waters, precise and timely food testing presents a growth opportunity that will remain in high demand for years to come. For NGOs, these are the types of challenges that confirm their value in supporting solutions for global problems. From a policymaker's perspective, harmonized standards provide relief to an overstretched regulatory and testing system and ensure that local growers and producers can access more global markets.

The first Green Revolution demonstrated we are capable of rising to the challenge of increasing food output. But the lesson learned from that success is quantity must be accompanied by quality to ensure true global food security. The global nature of our food system has resulted in both extraordinary benefits and significant new risks. Working together, we can all set in motion a second Green Revolution, and write the next chapter in our journey toward a sustainable food system and put us on track to achieve true food security. ■

Dr. Young is senior director, food and environment business operations, at Waters Corp. Reach him at 508-478-2000.

Around The World

Striving to Comply

Codex is the cornerstone of food safety in South America, but FSMA is a growing priority

BY **LINDA L. LEAKE, MS**

Editor's Note: *This is the fifth in a six-part series of articles that will showcase food quality, safety, and regulatory issues of each continent.*

From innovative Incan terraces on steep mountain slopes where potatoes and peppers flourish in Peru's iconic Andes range, to the vast pampas of Argentina where the legendary gauchos herd cattle on horseback, to prolific coffee plantations in Brazil's subtropical southeastern states, and to equally unique destinations in between, South America abounds with places where a tremendous variety of great food is produced for locals and the world.

"South America is strong in natural resources for food production," says Marisa Caipo, PhD, the Santiago, Chile-based food safety officer for the Food and Agriculture Organization of the United Nations (FAO) Regional Office for Latin America and the Caribbean (LAC). "The continent is also strong in innovative approaches on the part of large food exporters, as they typically respond positively and efficiently to trends in global food markets."

The continent's unique characteristics include a great diversity of food products, including super foods, like quinoa, amaranth, purple corn, and acai berries, Dr. Caipo continues. "What's more, food is produced in different seasons here than in Northern hemisphere continents, and this contributes favorably to the consistency of foreign food supplies year-round," she points out. "Spanish is a common language in South America and throughout the LAC region, which makes communications feasible among stakeholders."

South American countries export a wide variety of foods to the U.S., including fresh fruits, salmon, beef, wine, and coffee, among others, says Jairo Romero Torres, MS, a Bogota, Colombia-based food engineer and international consultant on food safety risk management and sanitary and phytosanitary (SPS) measures. To that end, he too boasts that some of the strengths and unique characteristics of South American products are that they are delicious and available in the U.S. off-season. "They also travel shorter distances than foods coming from other continents, so they are fresher, and some of them have very attractive prices," he adds, noting that "the seriousness of most of our exporters is well appreciated in the U.S. markets."

The U.S. imported a whopping $18.509 billion worth of agricultural and fish products from South America in 2014, according to U.S. Census Bureau trade data compiled by the USDA.

Market access throughout the world and brand protection have been the major drivers of food safety in South America, Romero Torres emphasizes. "As a result," he says, "actualization and implementation of new food legislation, as well as modernization of food safety inspection agencies to comply with international requirements and guidelines have been on the agenda of most countries in the region in recent years, all as a consequence of globalization."

On the downside, since food safety efforts in South America have been devoted to cultivating export markets, food for domestic consumption does not necessarily have the same requirements nor the same quality and safety as exported foods, Romero Torres points out. "But the continued exposure to specialized markets realized over the last 15 to 20 years is contributing to improving our resources," he says. "Now we have more food safety experts, better laboratories, more experienced food safety authorities, better rulemaking processes, and more training on food safety and qual-

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ity than ever before. Food safety is definitely a hot topic in many public and private scenarios."

Romero Torres observes that agriculture authorities, more than health authorities, have led this change in food safety regulation and inspection in the region. "That's probably due to the importance of food safety for growing food exports, which defines a very close relationship between food safety and agricultural development," he explains.

According to the FAO "Food and Nutrition in Numbers 2014" report, the LAC region is indeed a strong exporter of food, with 2011 exports of U.S. $112 billion. (In comparison, Asia's 2011 exports were U.S. $142 billion.) Imports in the LAC were U.S. $52 billion in 2011.

The World Trade Organization (WTO) reports that South and Central America exported a combined U.S. $217 billion in agricultural products in 2013, and Brazil alone ranked third globally in 2013 behind the European Union and the U.S., with U.S. $82.1 billion in exports of agricultural products.

Codex Commonality

The entire LAC region is composed of more than 30 countries, each with differing levels of advancement in their food safety characteristics, Dr. Caipo says, but basically all share membership in Codex Alimentarius.

Established in 1963, the Codex Alimentarius, or the food code, has become the global reference point for consumers, food producers and processors, national food control agencies, and the international food trade. Codex standards are based on the best available science assisted by independent international risk assessment bodies or ad-hoc consultations organized by FAO and the World Health Organization.

The 12 sovereign South American countries are all members of Codex. These include Argentina, Bolivia (Plurinational State of), Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, Uruguay, and Venezuela (Bolivarian Republic of).

Codex standards, while being recommendations for voluntary application by members, serve in many cases as a basis for national legislation, including in South America, Dr. Caipo relates.

On the downside of South American (and LAC) food safety, there is a need to increase political will to strengthen intraregional trade and local food chains, including short circuits and/or indigenous foods, Dr. Caipo says. "Lack of financial resources for food safety research in science-based decision making in South America and the LAC region is a problem," she mentions. "There is also a need to strengthen prevention and response to food safety emergencies. This is compounded by inadequate support and training in food safety at different levels of the food chain, for example, for consumers and street vendors."

"Street food preparation and sale remains a problem in several countries of the region," says Fernando Quevedo-Ganoza, PhD, CFS (Certified Food Scientist), founding director of the Latin American Center of Food Bacteriology Teaching and Investigation (Centro Latinoamericano de Enseñanza e Investigación de Bacteriología Alimentaria) and principal professor of food safety at the National University of San Marcos in Lima, Peru.

"Many markets and food service sites lack the conditions required to ensure the safety of food sold or served," Dr. Quevedo-Ganoza relates. "However, health authorities, as well as public institutions, show great interest in food control and in reducing the number and frequency of foodborne illnesses."

"Food safety at home and in food service operations, where most of the documented outbreaks are reported, are a major issue in South America," Romero Torres concurs.

"Infant diarrhea, with most cases caused by contaminated food or water, is a major concern for public health authorities," Dr. Quevedo-Ganoza says, adding that in South America, foodborne diseases are among the most prevalent illnesses, not only in children, but also in adults. "Such cases are often attributed to traditional indigenous foods and beverages prepared at home by low income individuals, often under less than optimum hygiene conditions."

> ...FSMA and other U.S. food regulations are greatly impacting food production systems in South America with ever increasing alacrity...

Coordination Issues

Most national food control systems in South American countries involve several ministries, and, thus, coordination among different agencies can be challenging, according to food microbiologist Bernadette Franco, PhD, a professor in the Department of Food Science and Nutrition and provost of graduate studies at the University of São Paulo, Brazil, as well as director of the Food Research Center, also located in São Paulo.

"Most countries in South America, in fact all of Latin America, are making efforts to align regulatory frameworks with the requirements of the WTO/SPS/Technical Barriers to Trade agreements," Dr. Franco says. "Moreover, these countries are actively seeking trade facilitation mechanisms, such as use of equivalence agreements for sanitary registration. It is important to note that there is a continuous need in Latin America to build capacity related to food safety and risk analysis and a continuous need to strengthen laboratory networks."

Despite existing inadequacies, according to Dr. Quevedo-Ganoza, South American countries have made great efforts to improve and increase their control and regulations relative to food.

Complimenting these regulatory efforts, some universities, including the National University of San Marcos, offer courses in hygiene, food microbiology, and food safety, and they train professionals specializing in these issues.

Also in South America's food safety plus column, a good number of food exporters have been accredited in various systems of quality management and many of them have been accredited as they apply the Hazard Analysis and Critical Control Points System, Dr. Quevedo-Ganoza says.

"The proof of success is that there has not been a significant increase in the number of rejections or withholdings of South American food products by U.S. Customs in the last decade," he

relates. "It is also important to note that many companies strive to meet U.S. FDA requirements dictated in the year 2002 to prevent the menaces and risks of bioterrorism, as well as those indicated in FDA/USDA Good Agricultural Practices dictated after the 1997 confirmation that foods of vegetable origin are as dangerous as those of animal origin."

FSMA Challenges

Despite the time that has passed since the publication of the Food Safety Modernization Act (FSMA), FSMA requirements have not been readily understood enough by South American food producers to be used as a guide on the continent, Dr. Quevedo-Ganoza adds.

"In many South America government departments, previous FDA food safety legislation continues to be applied," he relates. "It is important to reiterate that Codex Alimentarius standards are well known and routinely implemented by food manufacturers in South America. However, several major food exporters to the U.S. have been advised by U.S. food safety experts to interpret and comply with the mandates of the FSMA, and such compliance is continually growing here."

Since South American countries are net exporters of food and food products, and the U.S. is for some countries in the region the most important market, FSMA and other U.S. food regulations are greatly impacting food production systems in South America with ever increasing alacrity, Romero Torres adds.

"FSMA brings new and more stringent requirements for those who want to sell their products in the U.S.," he says. "To pass a FDA inspection will demand from many of our plants additional investments in terms of facilities, procedures, documentation, expertise, food analysis, inspection and certification, and other items. To pay for those substantial investments and increased costs, companies will have to be more efficient, improve risk management and risk mitigation strategies, and probably the prices of the products we export will have to increase. This means, the cost of those investments will have to be shared by the producers and the market as well, or else we won't be able to maintain or grow our participation in the U.S. market. That said, South American food processing companies are adapting their systems to the new FSMA regulations as the regulations are being released in the U.S."

Romero Torres is quick to point out that complying with the new FSMA regulations requires huge efforts in various fields, including institutional strengthening, application of risk analysis, a more science-based approach to production and control, data collection, and so on. "Some South American countries are more willing than others to adapt their production/regulation systems to the new FSMA requirements and, some act more rapidly than others," he says, "so the opportunities and challenges will bring different outcomes to different countries and different food sectors." ■

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For bonus content, go to August/September 2015 issue on www.foodqualityandsafety.com and click on "Food Safety in South America."

The Genomic Era Is Here

Whole genome sequencing network enhances foodborne pathogen traceability and the tracking of microbial contamination back to source

BY **MARC ALLARD, PHD, ERROL STRAIN, PHD, RUTH TIMME, PHD, HUGH RAND, PHD, JUSTIN PAYNE, DAVID MELKA, PALMER ORLANDI, PHD, PETER EVANS, PHD, V. KELLY BUNNING, STEVEN MUSSER, PHD,** AND **ERIC BROWN, PHD**

FDA has created and applied in real time public health use, a U.S.-based open-source whole genome sequencing (WGS) integrated network of state, federal, and commercial partners. The network, known as "GenomeTrakr," represents the first distributed genomic food shield for identifying and tracing foodborne outbreak pathogens back to their source. In only its third year, GenomeTrakr is already enhancing investigations of outbreaks of foodborne illnesses and compliance actions, enabling more accurate and rapid recalls of contaminated foods, and monitoring of preventive controls effectively in the food manufacturing environment. The resulting public genomic database of foodborne pathogens can support dramatically investigators ability to link specific food products, processing sites, and farms, providing valuable insight into the origin of the contaminated food. GenomeTrakr essentially creates a searchable, digital high-resolution fingerprint of the complete genetic make-up of individual pathogens, permitting otherwise indistinguishable bacteria to be easily separated and identified.

"This [database] is clearly the most powerful approach yet developed for tracking and tracing pathogens, and we expect it to have a very significant positive impact on food safety," says Steven Musser, PhD, deputy director for scientific operations at FDA's Center for Food Safety and Applied Nutrition (CFSAN). Considering the limited number of FDA food inspectors and the global nature of the food supply, the development and continual building (adding sequences and metadata) of GenomeTrakr is essential.

The food safety impacts of this network are impressive. Its current membership includes 30 public health, food safety, and academic laboratories from federal, state, and international stakeholders. The network has already shown great promise in enhancing the traceability of food and feed supply contamination events at the national level including *Salmonella* and *Listeria monocytogenes*. Moreover, WGS of microbial pathogens is now supplanting traditional microbiological analytics with rapid single data output summaries for antimicrobial resistance profiling, detection of high risk virulence profiles, and general identification strategies that supersede serological, phenotypic, and classical culture testing making the technology critical for an effective public health response to bacterial outbreaks.

An Important Role for WGS

Recent devastating outbreaks associated with consumption of fresh-cut produce have reinforced the notion that foodborne disease remains a substantial global challenge to public health. Mitigating foodborne illness, at times, seems an intractable challenge. One longstanding problem is the ability to rapidly identify the food associated with the outbreak being investigated. Despite the best efforts of food safety experts, the tools available for tracking foodborne outbreaks were sometimes too slow or uninformative to effectively pinpoint the source of the outbreaks. With the limitations of traditional subtyping methods, federal public health and food safety laboratories are exploiting WGS to delimit outbreak scope, traceback to point source, and make early predictions about important traits that a pathogen may harbor such as antimicrobial resistance. Highly parallel robotic genomic sequencers can sequence the DNA of a bacterial pathogen in a matter of hours. When coupled with validated, analytical bioinformatic pipelines such as the one established by FDA's CFSAN, accurate and stable genetic changes can be identified that can distinguish foodborne outbreak strains down to the source level including specific farms, food types, and geographic regions.

Eric Brown, PhD, director of the division of microbiology at CFSAN, compared the application of WGS for delimiting foodborne outbreaks to the impact that the Hubble Space Telescope had on our understanding of galaxies. "Can you imagine how astronomers felt the day the Hubble sent back its first pictures of the universe? This is exactly how we felt in 2009 when we applied WGS for the first time to a *Salmonella*-induced foodborne outbreak."

Numerous recent published examples illustrate the ability of WGS to discern high-resolution genetic relatedness of otherwise indistinguishable isolates. Proof of principle studies have been undertaken using the technology at numerous public health institutes both nationally and internationally. So much so, the success of WGS for rapid source tracking of pathogens is now well documented. In 2012, 425 individuals in the U.S. became sick from ingesting food that contained either *Salmonella* Bareilly or *Salmonella* Nchanga. Through traditional epidemiology methods, the illnesses were ultimately linked to a frozen raw yellowfin tuna product known as Nakaochi Scrape, which had been imported from India. (Nakaochi Scrape is tuna backmeat that is scraped from the bones of tuna and may be used in sushi, sashimi, ceviche, and other similar dishes.)

As part of the outbreak investigation FDA performed WGS on *Salmonella* isolated from product samples and from clinical samples to determine their DNA makeup. This data helped to more accurately determine which illnesses were part of the outbreak and which illnesses were similar but unrelated. However, FDA also did something else—a retrospective analysis. It performed WGS on about a dozen *Salmonella* Bareilly isolates stored in freezers from previous *Salmonella* Bareilly food contamination events. What FDA found was that the *Salmonella* Bareilly DNA for the samples tied to the 2012 outbreak was very similar to the *Salmonella* Bareilly DNA isolated from shrimp that came from a processing plant in southwest India several years earlier. In fact, the plant that processed the Nakaochi Scrape was only about five miles away from the plant that processed the shrimp. This observation was significant as it indicated that the paring of genomic information with geographic information might have the potential to be a powerful tool for traceback investigations. This event provided the impetus for creating the GenomeTrakr network and the increased use of genomic information in foodborne outbreak investigations.

As noted by Marc Allard, PhD, the genomics-area coordinator for CFSAN's microbiology program, "Our freezers are virtually full of *Salmonella*, *Listeria*, and other enteric pathogens collected as part of FDA's own inspection and sampling work. These collections represent a virtual treasure trove of genomic diversity and are invaluable as reference strains in an ever-expanding whole genome sequencing database."

GenomeTrakr: The Basics

In late 2012, FDA launched its GenomeTrakr network, the first distributed WGS network focused on the development of a highly informative, metadata rich, and fully transparent WGS database of environmental and food-associated enteric pathogens. In short, this database was launched to enhance our ability to use WGS

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Genetic Resistance to Wheat Disease

A recent study co-authored by University of Nebraska-Lincoln (UNL) researchers has unearthed the genetic roots of resistance to a wheat disease that has recently devastated crop yields from southern Africa through the Middle East.

Though reports of stem rust date back to biblical plagues and ancient Greece, plant breeders successfully combated the disease by introducing rust-resistant cultivars in the mid-20th century. Stem rust epidemics largely faded until 1999, when a mutated strain—Ug99—emerged in the east African country of Uganda.

Ug99 and its recent variants have toppled nearly all previously resistant genes. The rare holdouts include Sr2, found in an especially hardy wheat variety named Gage that was co-released by the University of Nebraska and the USDA in 1963.

The study isolated and examined DNA sequences of Gage to ascertain why it enjoys greater resistance to stem rust, including Ug99, than other cultivars featuring the Sr2 gene. The authors concluded that Gage's rust-resistance during adulthood likely owes to a combination of Sr2 and an additional gene, which the team believes also contributes to the wheat's resistance in the seedling stage of its development.

The researchers have narrowed down the location and potential identity of this additional gene, which they said they hope to soon verify through further study.

"It so happens that the source of Sr2 that was used to create Gage—the variety Hope—actually had a number of other stem rust resistance genes in it," reports P. Stephen Baenziger, PhD, a co-author and the Nebraska Wheat Growers Presidential Chair at UNL. "Our results would say that it looks like Gage got the lucky straw, so to speak, from Hope."

Drawing a genetic map to that level of resistance could prove extremely valuable against Ug99.

"It's important to understand the resistance to stem rust, because with the mutations that are coming out of Africa, we're losing genes all the time," says Dr. Baenziger. "But Sr2 is still resistant to it, and now that we can associate parts of the genome with the resistance, we're making good progress."—*FQ&S*

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to track foodborne pathogens. The network has created a publicly accessible global database containing the genetic makeup of thousands of foodborne disease-causing bacteria. CFSAN and the National Center for Biotechnology Information (NCBI) at the National Institutes of Health (NIH) collaboratively developed the necessary database and associated software tools. Much of this development continues to make genomic analysis more fully accessible to end-users from federal, state, academic, and industry sectors. Many of the state labs also are members of the Food Emergency Response Network putting them directly into many investigations of food contamination events. Our goal is to further enhance the network by growing the database while also adding more partners from public health, clinical, and regulatory agencies around the country as well as internationally.

The GenomeTrakr was originally comprised of labs in FDA/CFSAN, nine FDA Office of Regulatory Affairs field labs, and public health or agricultural labs from four states including New York, Florida, Washington, and Arizona. Data curation and bioinformatics support was provided by NCBI at NIH. In 2013, GenomeTrakr added labs from Minnesota and Virginia, and in 2014, brought onboard labs in New Mexico, Maryland, and Texas, and another New York lab. In addition, the CDC, USDA's Food Safety and Inspection Service, academic departments of veterinary science and agriculture, public health laboratories, and several other state-related groups have now acquired WGS technology and are actively collaborating with FDA in the sequencing of food and environmental isolates of *Salmonella*, *Listeria monocytogenes*, and Shiga toxin-producing *E. coli*. Most of these laboratories are equipped with Miseq desktop sequencers, and CFSAN provides technical support for wet-lab and bioinformatic methods and a web-based communication tool for real time data sharing. Currently, sequences are streamed from individual state laboratory Miseqs to a CFSAN computer where they are quality checked and formatted for upload to the GenomeTrakr database. CFSAN is working with NCBI and commercial software vendors to develop simpler tools that will allow individual laboratories to add sequences to the public database directly.

A Paradigm Shift on Two Fronts

Everyone who has seen the potential of WGS applied to food safety microbiology realizes that the technology brings huge paradigm shifts for how enteric pathogens will be tested and how they are tracked back to their source. The first paradigm shift includes using the increased resolution from WGS to intervene earlier in investigations. The second paradigm shift involves the new ability to link isolates across multiple years, whereby low-level contamination events can be linked across geographic time and space. However, there is a third paradigm shift and it relates to how information is shared. The GenomeTrakr database is public, meaning that anyone in the world can freely contribute and obtain information from it.

"People like to focus on the technology as the paradigm shift but, in my opinion, a really important advance is the open data-sharing model," exclaims Ruth Timme, PhD, FDA senior scientist and GenomeTrakr network principal coordinator. Of course, this approach would not prevent some aspects of the metadata to be held by individual organizations because of concerns about public release of proprietary information. The open database also allows FDA to go beyond the development of a source-tracking scheme. Several additional applications and benefits of the technology include: readily available antimicrobial resistance profiling to 98 percent accuracy; serological characterization without a need for classical antibody testing; virulence pathogenicity assessment for emerging bacterial pathogens; and, of course, high resolution subtyping, which has been its most widespread application to date.

"WGS is good because it can dig down deeper and identify the specific isolate and tell investigators what area or producer it could have come from," says Capt. Palmer Orlandi, PhD, senior science advisor in FDA's Office of Foods and Veterinary Medicine and member of the Commissioned Corps of the U.S. Public Health Service. Sample collection and sequence cataloging from food production sites can help monitor compliance with FDA's rules on safe food handling practices and enhance preventive controls for food safety.

Ultimately, sequencing capability should be distributed to as many sites as possible so that public health laboratories can move sequences from their collections and current surveillance and inspection activities into the database as quickly as possible. Dr. Allard emphasizes that "this public approach provides useful data to industry and academic partners, as well as to any federal or international agency that wishes to add value to the collected data." The current GenomeTrakr database contains sequences from roughly 14,000 *Salmonella* isolates and more than 3,300 *Listeria* isolates, and is growing by more than 700 new draft genomes per month. New phylogenetic trees showing emerging linkages and relatedness are produced daily by NCBI and are publicly accessible.

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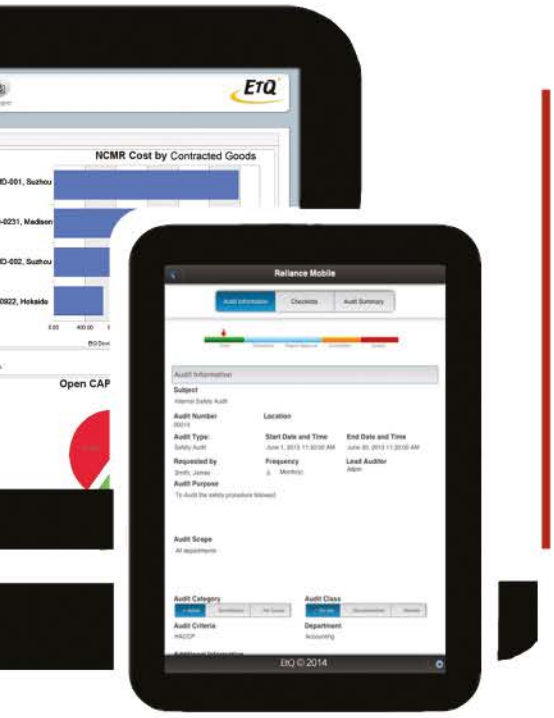

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Casting a Broad Net

The GenomeTrakr has already expanded and benefitted from other important WGS projects being carried out by public health experts in the U.S. and abroad. The CDC's Real-Time *Listeria monocytogenes* WGS pilot, which is sequencing all clinical cases of *L. monocytogenes* reported by the states since the fall of 2013 to enhance surveillance, is an example. FDA and other GenomeTrakr sites are working with CDC by contributing genomes of all food and environmental *L. monocytogenes* to the database. The work is making great strides in public health officials' efforts to delimit illness clusters and sources of contamination caused by this dangerous pathogen.

Errol Strain, PhD, CFSAN's lead bioinformaticist, puts a finer point on the importance of the collaboration with CDC. "To be able to go beyond what we once thought was a typical *Listeria* outbreak and now detect the outlying and more subtle contamination events caused by this pathogen is hugely impactful to food safety and public health." This real time collaboration has increased the number of *Listeria* outbreaks discovered and characterized, and has reduced the time to detection and increased regulatory activity for this pathogen in a significant way.

While tracking and tracing foodborne outbreaks is a primary application of the GenomeTrakr network, it is essential to note the broad important uses of such a database to food safety stakeholders. For instance, academic and environmental microbiology partners are using the database to accumulate broad amounts of genomic information on enteric pathogens that thrive in and around agricultural environments. Technology partners are mining these data for novel genetic targets to incorporate into assay design for improved pathogen detection systems, and industry partners are using the technology to mitigate safe food production and processing systems. Effective monitoring of supply chain ingredients means downstream cost and material savings for industry if they catch problems earlier and understand the root cause of the contamination event so that they can fix the problem and prevent it from happening in the future. Moreover, being able to distinguish between resident, facility contaminations versus a reintroduction of a pathogen strain from raw materials is a hugely beneficial application of the technology as the preventative solutions are different depending on where the contamination is coming from. Finally, the cost savings potential through monitoring with high certainty and with multi-analytes in one test cannot be overstated.

What's Next

Through numerous earlier case studies gathered from 2009 to the present and now weekly regulatory decision making, it is clear that WGS is validated and reproducible. Moreover, WGS will be adopted globally as the new method for foodborne pathogen surveillance and characterization. To be universal and comprehensive, more states and countries need to be added to the database and there needs to be a harmonization of the different networks being built both nationally and internationally. More work still is needed for successful implementation of a global food shield including: increased funding for instrumentation and training; issues surrounding data and metadata release into the public domain; harmonization among different authorities with sometimes distinct mandates and conflicting missions; and finally issues regarding validating alternative informatics approaches to interpreting the data. None of these barriers are insurmountable, and many believe it is only a matter of time until we will see a global food shield.

In Closing

The years 2014 and 2015 are watershed years for the use of WGS for food safety and public health in that many firsts were encountered as WGS left the research arena and entered into regular production and use across many state, federal, and international food safety agencies. Numerous successful applications of pathogen surveillance and characterization among academic, industry, and government partners has made WGS more prominent than ever and it has never been more apparent that the future lies with this technology. One can expect additional applications and greater impact as more partners join these efforts. These initial investments into the GenomeTrakr network, the new WGS technologies, and the hard work of many public health professionals are truly transforming the public health paradigm and these improvements will have long lasting benefits for the public and food safety. ■

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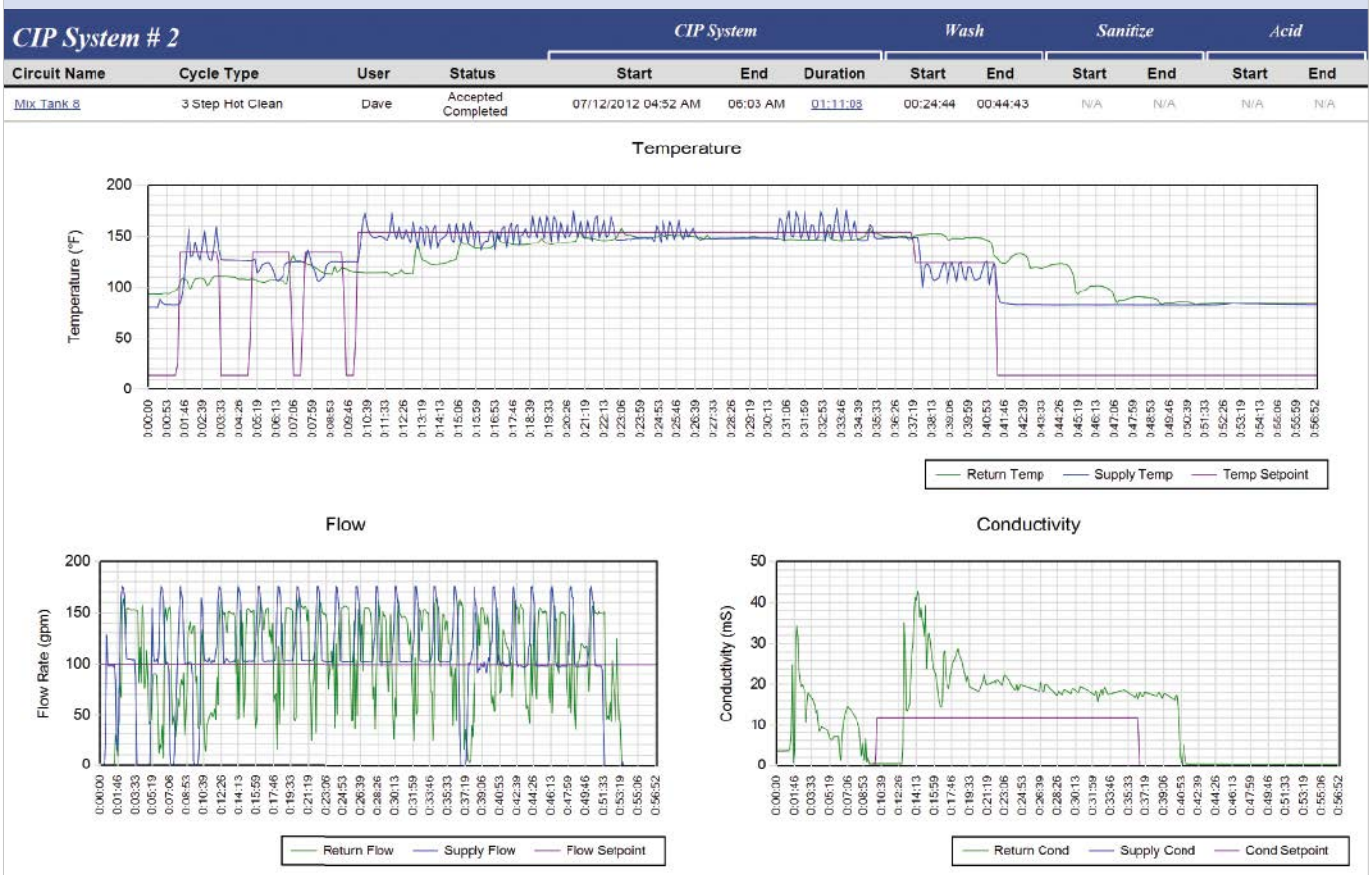

CIP System # 2

				CIP System			Wash		Sanitize		Acid	
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CIP trend report.

Modern Trends in CIP Automation

Apply these trends to new and existing clean-in-place systems to safely optimize production

BY **DAVID MCCARTHY**

A clean-in-place (CIP) system is like a washing machine connected to your food processing equipment. When fully integrated with a modern automation system opportunities abound for increased production capacity, enhanced product integrity, and significant savings in time, energy costs, and chemical expenditures. If you are interested in getting more out of your processing equipment, here's what you need to know.

The CIP Basics

A CIP system is comprised of dedicated equipment for the rinsing, washing, and sanitization of the interior surfaces of your process equipment. In these systems you will usually find tanks, valves, pumps, heat exchangers, chemical dosing, and process instrumentation devoted to this purpose. A single CIP system usually cleans a variety of processing equipment items and areas.

The connection between a CIP system and your process equipment is through a

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series of pipes, valves, and/or flow connection plates. These systems create and circulate various cleaning solutions through your process equipment. They generally monitor and record contact time, flow rates, temperatures, and chemical concentration levels to insure your equipment is properly cleaned. As the name implies, the CIP system and the equipment you are cleaning remain in place, and are generally not disassembled in any way as part of the cleaning regimen.

Compare this to a manual cleaning process. With this method your process equipment needs to be disassembled by hand; manually washed, rinsed, and/or sanitized; then reassembled when complete. For larger items like tanks, this likely requires rinsing down the tank, manually scrubbing the interior with a wash solution and brush, and then manually rinsing it off when complete. These methods are time consuming, and carry some risk to product integrity if the manual cleaning is not performed properly. For very large tanks, a manual approach may not even be possible.

A half step between CIP systems and manual cleaning operations are clean-out-of-place (COP) systems. There are a few different forms these systems can take. They may be stationary units with one or more tubs where equipment can be immersed with heated rinse solutions or detergent mixtures. There are also portable units usually comprised of a tank, pump, and heat exchanger that can be connected to stationary equipment. Depending on the system there is often some rudimentary automation or sequencing of the COP system, but it will generally require some manual operations to complete your cleaning process.

What's Your Type?

Now that you understand the basics, let's take a closer look at how a CIP system operates. Like your washing machine, these systems have historically been pre-programmed with a variety of generic cycle types. You will usually get cycles for things like rinse only, full wash, and sanitize only. Each cycle is comprised of a series of steps for things like filling the system, adding chemicals, heating and circulating solutions, rinsing the system, and draining. Each step is performed for a period of time, or until some event or measurement value is sensed by the system. Customizing these cycle types and matching them to the cleaning tasks at hand is one way a modern automation system can create more production capacity for your equipment.

Different products have differing effects on the soil levels of food processing equipment. For example, it is generally harder in a food plant to clean a batch tank that made chocolate pudding than the same tank that made vanilla pudding. This effect is not limited to just the batch tank, but also holds true for all of the processing and filling equipment involved in the production operation. The same equipment, running different products, can have different optimized CIP cycles.

Early CIP systems typically had a one size fits all group of cycle types. Modern automation systems allow for the individualization of CIP "recipes" very similar in concept to batch system recipes. For each product that is produced on a given set of processing equipment, there is a unique corresponding CIP recipe associated with that product.

Different sets of processing equipment, making the same product, may also have different cleaning requirements. For example, you may have a group of 10 tanks, all the same size, all capable of making the same product. The tank nearest to the CIP system may be 300 feet closer than the farthest tank. The closer tank requires less cleaning solution to fill the pipe to and from the CIP system, will lose less energy, and will generally use less cleaning chemicals compared to the farthest tank. The same product, made with different sets of processing equipment, can have different optimized CIP cycles.

A modern automation system will also optimize cleaning times based on such factors. In the batching world a master recipe is generally executed on a number of different batch tanks. CIP recipes operate in a similar manner. When they are run on a particular piece of equipment, the system individually adjusts the master CIP recipe to optimize for differences based on physical location factors as described above.

CIP recipe optimizations that match what you make to where you make it can yield significant savings in cleaning time and costs. While the costs savings are interesting to everyone, the time savings can be of particular interest if your plant is capacity constrained. Such cleaning time reductions produce in effect more production capacity from your existing processing equipment.

Safety First

Managing allergenic and gluten cross-contamination is a top priority for food processors. An automation system can assist with product scheduling to mitigate these risks, while optimizing your overall production capacity. It does so by coordinating the operations of the automated CIP system with the automated production equipment.

Complicating any scheduling process is the requirement to sequence the manufacturing of certain product types in specific orders. For instance, with no intervening cleaning it may be permissible to follow a vanilla pudding product run with chocolate pudding. Reverse the production order, and residual traces of chocolate color could ruin your vanilla product. Of even greater concern is the potential for allergenic/gluten cross-contamination from one product into another.

A CIP matrix editor brings the production and cleaning operational areas together. All product types are listed in both rows and columns. One group defines the previous product run, and the other the next run. The matrix point where each product type meets defines the cleaning requirements between these runs. These requirements can range from none at all where one product can freely follow the other; to a short rinse required between product runs; to full scale long wash requirements; or anything in between.

The trend in many food manufacturing facilities is processing an ever increasing number of SKUs. It is often difficult and time consuming to put together the optimum production schedule with these changing requirements. When combined with an automated production scheduler, a CIP matrix editor can be instrumental in developing the most efficient method to stage product runs based on your orders in hand.

During actual production, the automation system will use the CIP matrix data

to confirm the validity of the operation. When a production run is initiated every piece of applicable process equipment is first checked to insure the matrix requirements are met, or the run is disallowed. This production run configuration data is typically maintained and controlled by quality assurance, and cannot be overridden by operations staff.

This is another way a modern automation system can squeeze more capacity out of your processing equipment. Optimizing your production run sequence by minimizing intervening cleaning operations allows for maximum production time on a given line. It can do this while monitoring these operations to mitigate the risk of ingredient cross-contamination between runs.

Big Data to the Rescue

The plummeting cost of information storage is enabling options in automation systems that did not exist even a few years ago. Modern systems will often utilize massive networked storage arrays to historize everything in a facility. This can entail recording from moment to moment every measurement, every device state, every automated operation, and every operator interaction on every terminal throughout the facility. While such data fingerprints can be critical to effective troubleshooting when something goes wrong, it can also be of great value for use in plant optimizations.

Big data can give a view of how your equipment is operating over an extended period of time. CIP operations of all types are logged in detail for each piece of processing equipment, every time the operation is performed. On a step-by-step basis, all of the details can be recorded, including the duration of each step; the amount and type of detergents and sanitizers utilized; energy consumption; and any other item of interest. These recorded step values are also aggregated across the entire cleaning operation. Looking at how this data changes over time can give insight into the operation of the equipment that might otherwise be difficult to see.

Linear regression analysis plots the best straight line through a series of data points. For example each data point might represent the total cleaning time for a given piece of processing equipment at a specific point in time. When analyzed over an extended period of time, trends concerning the effectiveness of these cleaning operations can emerge. If the linear regression line is rising, this indicates that the cleaning process is slipping out of control and in need of improvements. If the line is flat, the process is stable over time, although a large amount of high and low outlier values could indicate potential for improvements. If the line is falling over time, the efficiency of the process is improving.

This type of analysis could be useful in other ways. A data point could represent the aggregated total cleaning time for all processing equipment on a given day. How this changes over time can indicate the CIP effectiveness and impact on equipment availability across the entire production facility. Narrower views could be applied to specific processing areas or production lines. On the cost side, similar looks at chemical usage, energy consumption, and more is easily provided once the measured data is in place. In these examples rising regression lines indicate opportunity for increased capacity or cost reduction, falling lines indicate improvements.

Linear regression analysis is a great tool to stay ahead of any issues before they become real problems. It can also provide verification that your process improvement strategies are working as intended. In addition to CIP optimizations, this type of analysis could be applied across a wide spectrum of production operations.

The Modern CIP Approach

A modern automation system will unite your production operations with your cleaning operations to make them work together at peak performance. Cleaning recipes are developed based on product type, which adjust automatically for equipment particulars, to provide the most effective cleaning regimens for your process equipment. The upfront time developing these CIP recipes will pay dividends for years to come.

By managing the cleaning requirements between varying product types, modern systems will provide tools to simplify the increasingly difficult task of developing efficient production schedules. They can do this while monitoring actual production operations to mitigate the risk of ingredient cross-contamination. Finally, with the plummeting cost of mass storage, new and interesting analytical tools are now applied to CIP operations. When used properly they can yield greater efficiency and cost savings opportunities than ever before. ■

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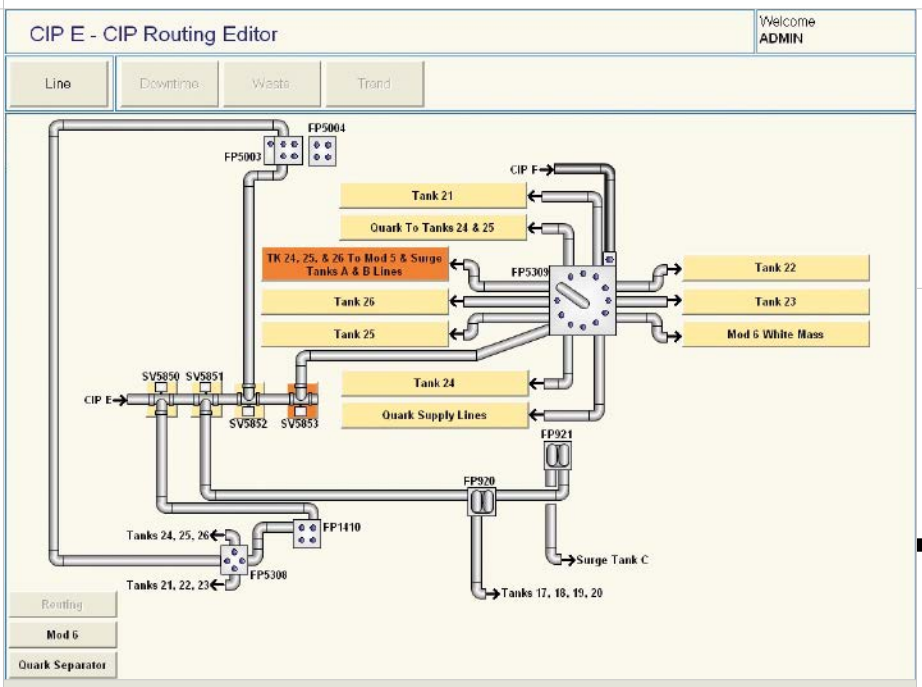

More Flexible CIP User-Configurable Solutions Are Here

Configurable systems combine optimization and programming functions to give manufacturers full control over adjusting and monitoring | BY **JOHN TERTIN**

Food and beverage manufacturers recognize that having proper clean-in-place (CIP) methods for closed systems is not only a regulatory requirement, but it also makes good business sense by ensuring consumer food safety and product quality.

What doesn't make sense are the current practices many manufacturers undergo in order to make changes to their CIP recipes, sequences, and procedures. Often this requires issuing request for proposals, securing approvals, involving sanitation or chemical experts, and waiting weeks for an optimization expert or otherwise other engineering resource to conduct an onsite visit and perform a straightforward change.

Time is money, as every manufacturer knows. Clearly something better, faster, cheaper, smarter, and simpler is needed.

Enter newer, configurable CIP systems that empower manufacturers by bringing optimization and system design together in one automation solution. Typically, optimization and programming are two functions approached separately. When combined into a single solution, however, the automation gives manufacturers full control over adjusting and monitoring their CIP systems without incurring the expense and inefficiencies that come with calling in outside programming or engineering assistance for each and every modification.

With the latest control and monitoring automation, manufacturers can themselves tweak and modify their CIP systems to create greater efficiencies, use fewer chemicals and less water, and decrease cleaning downtime. They can do it all, without having to call in external resources to incorporate their prescribed changes into the automated system.

Today's best configurable CIP solutions allow operators to adjust time, temperature, and flow at will. Such solutions also record all process parameters, collect information and recipe change history, and provide critical data to manufacturers, allowing them to generate insightful reports that help them remain compliant and competitive.

Today's best configurable CIP solutions allow operators to adjust time, temperature, and flow at will.

Configurability

The purpose of a CIP system is to transfer water and cleaning solutions from separate holding tanks to perform cleaning throughout process equipment following the end of a production batch. Typically designed as a three- or four-tank system, cleaning is performed and controlled by a series of vessels, pumps, and instruments that are divided into independent CIP circuits. Each CIP circuit will have its own unique sequence of operations and cycle times.

There are several factors that ensure controlled sanitation and CIP effectiveness. Fundamentally, it depends on time, temperature, flow velocity, and solution concentration, as well as the path of the flow, which is typically the most difficult to configure. A robust configurable CIP solution is one that offers an intuitive interface and gives manufacturers the ability to configure and control each of these cleaning variables as they recognize opportunities for optimization. Add in electronic recordkeeping and historical records, and quality assurance is further enhanced with detailed performance data and trending information.

When seeking a CIP solution, consider the ease and flexibility of being able to configure the following areas.

ESE.

Time, temp, and flow. Allows the operator to control when the step sequences will advance. A step can be held for a certain amount of time, for a specific temperature, a specific conductivity (chemical concentration), or until the operator manually advances the step.

Valve pulsing. Allows the operator to control when a valve is pulsed on and off during a wash. For example, an operator could choose a start time and an end time so as to configure a valve to pulse for 10 seconds every minute. Start and end times can be configured to accommodate the overlapping or staggering of several valves.

During wash. Provides visibility by highlighting the current path of the circuit as it is currently configured.

Steps. Shows the recipe steps as they are configured and allows operators to insert, delete, or edit steps as needed. When editing, operators access an interface that takes them to "Time Temp and Flow" or "Flow Plate Routing" so they can configure the exact devices that are active during each step. With maximum flexibility, operators can perform complete configurability right down to the individual devices—valves, pumps, proximity switches, temperature, and flow control, for example.

Flow plate routing. Allows operator to select the path the flow should take. In this example, when the CIP solution reaches a flow plate, it traverses through the middle port. The ports on the outside branch to different areas of the facility (see diagram on p. 26). Once the operator selects the path, there is a proximity switch in place to validate that the swing (the pipe that goes from the middle to the branches on the perimeter) is in the correct position. This is a requirement before the system can run and it prevents cleaning solution from flowing where it's not intended to be should an operator incorrectly position the swing.

In this diagram, valve V5853 has been configured to turn on during the step based on its orange color. This means that solution will come from CIP (at left), through valve V5853, then through the flow plate to the port supplying TK 24, 25, 26. This is how the entire circuit is defined.

Of course, ensuring compliance with food safety regulations requires documentation. Therefore, the right CIP solution is one that can collect documented evidence of proper sanitization and also provide key insights into optimization opportunities. Some relevant reports that can be helpful include:

- Revision report: captures every activity (change) made for a specific revision of a wash cycle;

With maximum flexibility, operators can perform complete configurability right down to the individual devices...

- Revision history: shows the history of all recipe versions for every wash;
- Operator activity report: shows activity on every system, including when washes were started, stopped, and reset; tracks system events, like alarms or operator comments that can be entered ad hoc at any time; and shows when operators step sequences forward or backward;
- Exceptions report: presents a record of exceptions/problems that occurred during wash cycles, including pump malfunctions, operator-initiated emergency stops, longer-than-normal time spent heating up to temperature, or any number of other alarm conditions; and
- Completed circuits report: provides a history of washes that occurred for each system, showing the circuits that were washed, when they were washed, the number of times an operator stepped forward or back in the sequence, or if the wash cycle was aborted (ended prematurely by the operator before the entire wash sequence could complete).

Become Empowered

By leveraging user-configurable automation so as to enhance CIP, today's manufacturers can reap many benefits. They include the ability to create flexible security control levels and recipe configurations without relying on engineering resources to implement the changes, obtain complete recipe traceability, gain detailed trending, reduce cleaning times, improve safety, log events and configurations, generate reports, and monitor performance over time using manufacturing information system tools.

In other words, with more control over CIP comes more productivity, lower costs, stronger compliance, greater self-reliance and added quality assurance. ■

Tertin, the director of manufacturing information solutions at ESE, Inc., is credited with developing ESE's MIS solution suite and for expanding the adoption of MIS solutions within ESE's customer base. Reach him at tertinj@ese1.com.

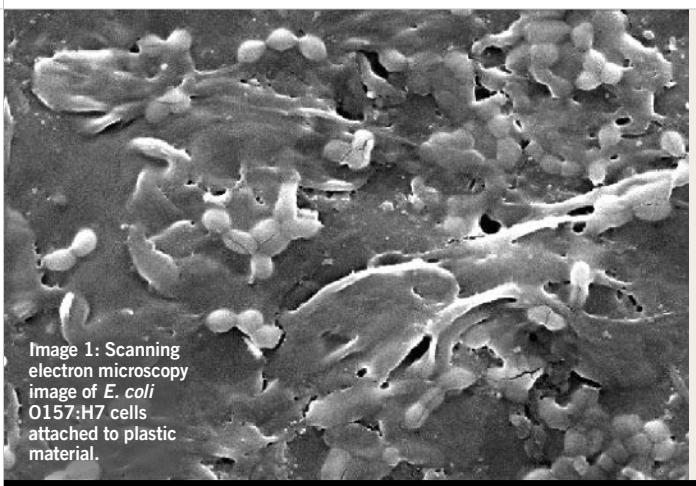

Image 1: Scanning electron microscopy image of *E. coli* O157:H7 cells attached to plastic material.

Biofilms, Processing Equipment, and Efficacy of Sanitization

The potential for bacterial attachment and biofilm formation is a problem for a wide range of surfaces that may contact fresh produce

BY **CHRISTOPHER A. BAKER**
AND **STEVEN C. RICKE, PHD**

In the past decade, several outbreaks related to fresh produce have occurred, and at least some of these factors that have contributed these outbreaks remain to be determined. Did any of these outbreaks result from the container the food was shipped in or the processing equipment that it came in contact with? Although detection platforms (real-time polymerase chain reaction, or PCR, and whole genome sequencing, among others) rapidly advance, it is unrealistic to analyze each factor that may have been associated with an outbreak. Food safety affiliates are left with many unknowns from these outbreaks, and the alternative approach to determine the level of risk posed by each factor requires sound scientific research.

The Changing Factors

Assessing the level and sources of risk remains a moving target. Many times there is a perfect storm that leads to produce contamination and a subsequent outbreak. Which factors contribute to this perfect storm? This is yet to be determined. Research for the correct answer will likely be warranted in years to come. Likewise, as our society continues to progress through sustainability measures, all of the factors that may lead to contamination from farm to fork should be assessed within the framework of limiting waste and becoming more sustainable. Balancing sustainability with food safety control measures remains a complex multifaceted challenge. For example, water use for sanitization of containers, processing facilities, etc. must be considered along with water conservation. Although recent research from National Oceanic and Atmospheric Administration suggests that droughts in California are primarily due to natural oceanic and atmospheric patterns, human water use practices may contribute to the likelihood of droughts. Therefore, processing facilities in the future may not have the luxury of excessive water-based washes to dilute for routine cleaning of equipment and reusable packaging containers and other services.

The game may change considerably in the coming years with regard to how industry sanitizes its equipment, and it seems that regulations will need to be adjusted in the case of a limited water supply. However, water and sanitizer application use is critical for achieving sufficient cleaning. Biofilms (and general bacterial buildup) are notorious for hanging on for dear life, proving removal efforts insufficient. Finding biofilm on surfaces such as processing equipment and shipping containers is threatening since they are likely to be continually reused, and can contaminate every product that it comes into contact with, thus creating a production line of contaminated fresh produce.

The Pathogens

Research is primarily focused on biofilms, but single attached cells could potentially contaminate a product, especially if these cells proliferate into a sufficient population. Fresh produce is typically uncooked before consumption, and depending on the consumer as well as the pathogen on the produce, only a few cells could lead to illness.

For instance, Shiga toxin-producing Escherichia coli (STEC) are notorious for leading to illness following exposure to a small number of cells, and based on past outbreaks, it seems evident that illnesses associated with ready-to-eat and fresh produce will likely continue. *E. coli* O157:H7 is infamous for the 1993 outbreak in the Northwest region of the U.S. This outbreak was linked to several deaths, and resulted from undercooking ground beef patties that were contaminated with *E. coli* O157:H7. The fact of the matter is that even if food products are contaminated with harmful bacteria, proper cooking and preparation practices (reaching an acceptable internal temperature and avoiding cross-contamination) will eliminate these pathogens, and foods can be consumed safely. Unfortunately, ready-to-eat raw foods such as fresh produce are seldom cooked before consumption, so the health risks associated with these products is much greater. Many Americans are making efforts to consume higher amounts of raw fruits and vegetables for a healthier diet, and the potential for illnesses is a major drawback to these uncooked products.

The Research

The ability of foodborne pathogens to attach to as well as persist on surfaces is a real concern. For example, a recently published manuscript in the Journal of Food Research suggests that attached cells may be able to withstand some of the sanitizers used in industry for cleaning procedures. One-inch squared coupons (plastic material) were exposed to a cocktail of *Salmonella* cells for a three-day period, rinsed thoroughly with water, treated with a variety

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of sanitizers, and subsequently swabbed in a way that simulates scrubbing for equipment cleaning procedures. Several treatments were evaluated, and although these treatments reduced levels of bacterial cells, none were sufficient to completely remove the attached *Salmonella* cells.

Attachment of cells to the plastic materials was analyzed with a scanning electron microscope. Like other microscopy techniques, scanning electron microscopy (SEM) is used to study particles (biological or synthetic) that cannot be visualized by the naked eye. SEM differs from other microscopy techniques in that a beam of electrons are emitted onto the surface or sample of interest. This causes secondary electrons to be emitted from the sample, and these secondary electrons are captured by detectors inside the scanning electron microscope, which ultimately transmits the signal into an image that can be viewed on a computer. SEM essentially assesses the topography of a surface as well as the materials on the surface being viewed. Although surfaces often times appear to be smooth, SEM reveals the complex structure of surfaces (see Image 2).

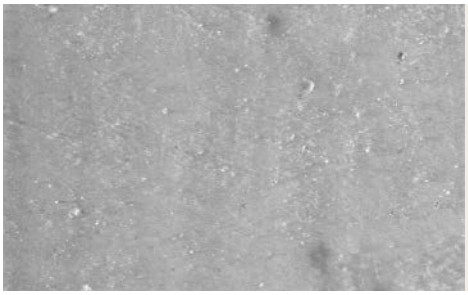

Image 2: Scanning electron microscopy image of plastic material prior to exposure of bacterial cells.

Since it is possible that these bacterial cells could be attached but dead, the plastic materials with attached cells were transferred to a nutritionally rich broth to support the growth of live bacterial cells. This procedure is commonly used to increase the number of bacterial cells that may be in a sample—once the enrichment procedure is performed, any live cells will theoretically be present at a population level, which can be evaluated by detection procedures. Once the plastic materials were enriched, the commonly used detection method PCR was performed. In short, specific DNA sequences (primers) are used to amplify target DNA (*Salmonella* in this instance) in a sample. Following PCR, real-time instruments can assess whether or not samples consist of the target DNA, and in this instance, thus providing information on which samples consisted of living cells. For each of the samples analyzed, all PCR reactions were positive for *Salmonella*.

Upon first glance at SEM images, a viewer would reason that these images resemble the terrain of a moon, and these cracks and crevices provide the opportunity for bacteria to set up shop and become established. Container surfaces are just one example of how easily bacteria could become widespread on surfaces throughout a processing plant if established. The potential for bacterial attachment and biofilm formation is a problem for a wide range of surfaces that may contact fresh produce.

What measures involve the most appropriate method of food transportation, primarily for fresh produce? Unfortunately, these answers are not fully understood, but as more research is conducted (and new methods work around a limited water supply), food safety measures will be developed to limit contamination on surface materials.

Spray of sanitizers, phage-particles, or even competitive biofilms of non-pathogenic bacteria may be useful for limiting the attachment of cells to surfaces. Our research indicates that the sanitizers used to sanitize plastic materials are not sufficient in removing attached cells visible by SEM, and much more research will be needed to determine the best approach for sanitization. As more research is conducted pertaining sanitization treatments on biofilms or single attached cells, the ultimate decision on cleaning approaches will require evaluating cost of effectiveness versus the level of acceptable risk. In short, there continues to be many unknowns with biofilms, and everyone needs to be careful with the claims they state since existing data sets may fail to tell the full story. Added to this dilemma will be the requirement that future food safety practices implemented will potentially have to work around water and other environmental limitations for equipment sanitizer treatments, as well as consumer acceptance. ■

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How to Fit Training Into Your Production Schedule: Part 4

Understanding where training fits into the corrective action and root cause analysis landscape can help prevent repeat problems from occurring

BY **MARGARET KOLK** AND **MARIE LEFAIVE**

Editor's Note: *This is the fourth in a five-part series of articles that will explore each concept behind the five moments of need in training.*

In earlier articles, we've discussed the first three moments of need: learning for the first time, learning more, and remembering or applying what we learned.

The fourth moment of training need, according to the performance support experts Conrad Gottfredson, PhD, and Bob Mosher, is when problems arise. We've all been there. We've all watched as a project or process, or even a conversation, goes horribly wrong. That first sinking feeling of "I can't believe this just happened" is quickly followed by its corollary "I wish I knew how to fix it."

Enter training.

Sometimes, learning how to fix a problem means signing up for a course. If your calculations were off in your woodworking project, maybe you need to take a geometry refresher. Other times, problem solving is as simple as buying a book on how to have difficult conversations.

The most critical training, however, is the one that is right there for you *at the time the problem occurs*.

In our industry, we actually have a number of processes in place to address just this eventuality. All food safety systems, for example, include corrective actions that prescribe exactly what to do when there is a food safety issue. They provide specific procedures to help you regain control of the process, ensure product safety, and document the event. They stipulate how to ensure compliance and who to train on conducting the corrective action. More and more, they also set down the conditions for conducting root cause analysis to prevent repeated reoccurrence of the problem.

So there it is, the fourth moment of need neatly wrapped up in a Hazard Analysis and Critical Control Points plan—our very own specialized job aid.

Except for one thing.

Corrective actions usually address only the immediate symptoms of the problem, and root cause analysis, when it is done, often points right back to training as the problem.

Why did the operator make a mistake? He wasn't trained properly.

Why wasn't this monitoring record completed? Because the worker did not follow the instructions. Why did she not follow the instructions? Because she wasn't trained.

Training becomes the scapegoat for what is often a far more systemic problem.

The Role of Training in Corrective Actions

Let's break this down a bit to see where training fits into the corrective action and root cause analysis landscape.

Imagine you work in a pie-making company. The temperature in the walk-in freezer falls below the acceptable level. What do you do? According to your company's documented corrective action procedure, you transfer the food to a second freezer, call maintenance to fix the freezer, and document your actions. If you have been onboarded to the procedure, this is a simple if annoying task. You may be a bit sloppy with the paperwork, but this is not a training issue. (Some corrective actions may be more complex, and dedicated training could be indicated. What to do when environmental swabbing of food contact surfaces yields unacceptable results comes to mind. But these are few and far between.)

Root cause analysis of our freezer problem shows that widget A malfunctioned, causing contraption B to overheat. The solution is to replace widget A. Again, no need for training.

Now imagine that this is the fifth time widget A has malfunctioned this year, and that maintenance actually keeps a stock of widgets in their storeroom. What should we make of this?

We should conclude that the root cause analysis process is lacking as it clearly did not reach the root of the problem. This lack of proper root cause analysis could be a training issue.

- Question: Why wasn't the root cause analysis more effective?
- Answer: Because no one was trained on proper root cause analysis methodology.
- Solution: Bring in training.

Without question, training in root cause analysis methodology makes sense. From a business perspective, allowing problems to reoccur is not a wise financial strategy. Auditors often cite a lack of proper root cause analysis as a significant problem. Effective root cause analysis requires a skilled team adept at searching for patterns in the data and dedicated to implementing long-term solutions.

The real issue here, however, is that we have once again accepted training as the final answer. To borrow from a classic root cause analysis tool, we should have asked at least one more why. Why was no one trained on proper root cause analysis methodology?

Why was no one trained on proper root cause analysis methodology?

There could be any number of reasons, including a high staff turnover and the company hasn't gotten around to retraining; there is no in-house expertise in root cause analysis and no budget for an outside training provider; or nobody really understands root cause analysis in the first place. All of these beg for one more why, and each one points to a far greater issue: Not retraining in a timely manner, not ensuring dedicated funds for critical training, and not bothering to understand a key component of your food safety system means that there may be a weakness in your company's commitment to food safety. This is not something that training alone can solve.

It can never be said enough: Training and management commitment must go hand-in-hand. Otherwise, like Sisyphus, you will be condemned to constantly push a rock uphill. To provide more than a Band-Aid solution at this most critical moment of need, work to get company buy-in. It will make your training investment a lot more worthwhile, and your training efforts much easier. ■

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Marine Biotoxins: Tasteless and Odorless

As increased consumption of seafood results in higher incidence of foodborne illnesses, research in the EU is underway to find ways to protect against these hard to identify biotoxins

BY **AMORNPUN DAJSIRIPUN**

Fish and shellfish, including species of mollusks, crustaceans, and echinoderms, contain high quality protein and other essential nutrients, especially omega-3 fatty acid, making seafood a popular meal choice. However, seafood contaminated with marine biotoxins can cause severe illnesses in humans, an issue that has been raised as critical for food safety. The European Union (EU) is monitoring the problem closely.

In addition to ingestion via food products, human health can be affected by exposure to marine biotoxins through contact with contaminated water or inhalation. Today, the global and often unpredictable distribution of these toxins can cause massive fish kills and long closures of harvesting areas, both of which adversely impact the aquaculture economy. Marine biotoxins are tasteless, odorless, heat stable, and unaffected by cooking, freezing, and drying. Finding ways to identify contamination and warn of toxin exposure is proving challenging for the scientific community.

Naturally Occurring Marine Biotoxins

Marine biotoxins, also called phycotoxins, are secondary metabolites produced by several microalgal species from dinoflagellates, when they rapidly multiply and produce blooms. Algal blooms that pose a hazard to the environment and/or humans are called harmful algal blooms. No cause for the blooms, or why they sometimes produce toxins has been identified. Aquatic mollusks with two-part shells, bivalve filter feeders consume the microalgal, and toxins then remain within their tissue. Phycotoxins tend to accumulate only in the digestive glands (hepatopancreas). Just six hours of filtration can be enough to make a shellfish toxic to human health.

Types of Marine Biotoxin and Health Impacts

Approximately 20 species of dinoflagellates and a smaller number of diatoms are currently known to produce phycotoxins. Based on human poisoning syndromes, phycotoxins in seafood can be classified as:

- Paralytic shellfish poisoning (PSP),
- Neurotoxic shellfish poisoning (NSP),
- Amnesic shellfish poisoning (ASP),
- Diarrhetic shellfish poisoning (DSP),
- Azaspiracid shellfish poisoning (AZP), and
- Ciguatera fish poisoning (CFP).

PSP. These toxins are fast-acting neurotoxins that can inhibit transmission of nerve impulses by blocking voltage-gated sodium channels in nerve, skeletal, and cardiac muscle fibers and finally lead to death by respiratory paralysis. All PSP toxins are alkaloids with a tetrahydropurine structure and two positively charged guanidine groups. To date, at least 24 derivatives of saxitoxin (STX) analogues have been discovered. These compounds are mainly produced by dinoflagellates *Alexandrium* spp., *Gymnodinium catenatum*, and *Pyrodinium bahmense*. With the substitution at four sites of STX and the N-hydroxy derivative neosaxitoxin (NEO) backbone, PSP toxins have been subdivided into four groups: carbamoyl toxins (STX, NEO, GTX1-4), N-sulfocarbamoyl toxins (B1-2, C1-4), decarbamoyl toxins (dcSTX, dcNEO, dcGTX1-4), and deoxydecarbamoyl toxin (doSTX, doNEO, doGTX1-3). In canned seafood, it is found that the hydrolysis of N-sulfocarbamoyl toxins to carbamoyl and decarbamoyl increases the PSP toxicity.

Recently, the novel hydroxybenzoate saxitoxin analogues have been isolated from *Gymnodinium catenatum* and designated as GC toxins. In their chemical

Table 1: Threshold values for marine biotoxins.

Toxin Groups	Reference Toxin	Current EU Regulatory Limits Implemented EC 853/2004 and 786/2013 (µg/kg of shellfish meat)	Codex Regulatory Limits (µg/kg of shellfish meat)
PSP	STXs	800 STX Eq	800 STX Eq
DSP	OA and DTXs	160 OA Eq	160 OA Eq
	PTXs	160 OA Eq	
	YTXs	3,750 YTX Eq	Unregulated
AZP	AZA	160 AZA Eq	160 OA Eq
ASP	DA	20000 DA Eq	20,000 DA Eq
NSP	BTX	Unregulated	800 BTX Eq
CTX	-	Not allowed	Not allowed

substituents, GC toxins are divided into monohydroxybenzoyl toxin (GC1-6), dihydroxybenzoyl toxins (GC1^{a}-6^{a}), and hydroxysulfated benzoyl toxins (GC1b-6b). Apart from GC toxins, new saxitoxin analogues, known as LWTX 1-6 toxins, are also found in cyanobacterium *Lyngbya wollei*. Furthermore, PSP toxins in mussels, crabs, and puffer fish can metabolize to M1-4, 11-saxitoxinethanoic acid and STX-uk respectively.

NSP. Brevetoxins associated with NSP are produced by dinoflagellates *Gymnodinium breve* and *Ptychodiscus brevis*. These toxins are divided into two groups (type A and B) based on their backbone structure. A-types consist of PbTx-1, PbTx-7, and PbTx-10 and the B-types are PbTx-2, oxidized PbTx-2, PbTx-3, PbTx-5, PbTx-6, PbTx-8, and PbTx-9. Of the brevetoxins, PbTx-2 is the most abundant, while PbTx-1 is the most potent. In shellfish, PbTxs are metabolized into more toxic compounds, for example, BTX-B1 and BTX-B4. PbTxs and BTXs act as depolarizing substances, which open voltage-gated sodium ion channels, leading to uncontrolled Na influx into the cells. Symptoms and signs of NSP are mainly gastrointestinal effects (abdominal pain, nausea and diarrhea) and neurological effects (ataxia, myalgia, paraesthesia and reversal of temperature sensation).

ASP. Domoic acid (DA) produced by red algae *Chondria* spp. and diatoms *Pseudonitzschia* spp. is responsible for a human illness known as amnesia shellfish poisoning. Due to the structural similarity of DA and kainic acid, it is no surprise that DA has an antagonistic effect on the glutamate receptor of the nerve cell terminal. Acute symptoms at high levels of DA exposure include vomiting, abdominal cramps, diarrhea, headache, seizures, respiratory excretions, and confusion as well as coma and death in some cases. Apart from DA, their isomers are also reported to cause an ASP effect. However, DA isomers are less toxic than DA.

Because of the potential hazard to humans, a quick, sensitive, and specific method is needed to determine the presence of marine biotoxins in seafood.

DSP. These toxins are polyether compounds produced by dinoflagellates *Dinophysis* spp. and *Prorocentrum* spp. They are also found in many filter feeders such as mussels, clams, and oysters. Depending on their chemical structure, DSP toxins can be divided into three groups: okadaic acid (OA) and dinophysistoxins (DTXs), pectenotoxins (PTXs), and yessotoxins (YTXs). Typical symptoms of DSP toxins are diarrhea, nausea, vomiting, and abdominal pain. Unlike bacterial diarrhea, the symptoms of DSP toxins may be severe and begin anytime between 30 minutes and a few hours after eating contaminated shellfish. OA and DTXs were reported as tumor promoters resulting from the inhibition of protein phosphatase. Unfortunately, non-diarrheic effects were shown in PTXs and YTXs after both groups were placed into DSP toxins. The EU has established a new regulation to separate PTXs and YTXs from OA and DTXs.

AZP. Azaspiracids (AZAs) are another class of polyether toxins associated with AZP. The chemical structure of AZAs consists of the unique spiro-ring assemblies, a cyclic amine and carboxylic acid. Five analogs, AZA-1, AZA-2, AZA-3, AZA-4, and AZA-5, have been isolated from dinoflagellate *Protoperidinium crassipes*. AZA-1 is the most toxic to humans, followed by AZA-2 and AZA-3. AZA-4 and AZA-5 are oxidized metabolites of AZA-3. Acute symptoms from human consumption of AZP contaminated shellfish are similar to DSP, including nausea, vomiting, diarrhea, and stomach cramps.

CFP. This is caused by consuming a large variety of tropical and subtropical fish contaminated with ciguatoxins (CTXs) and maitotoxins (MTXs). These toxins are mainly produced by dinoflagella, *Gambierdiscus toxicus*. CTXs are concentrated in both the viscera (e.g., liver, intestines, and gonads) and muscle, whereas MTXs seem to be confined to the viscera. CFP symptoms are characterized by moderate to severe gastrointestinal symptoms (vomiting, diarrhea, and abdominal cramps), neurological signs (myalgia, paraesthesia, cold allodynia, and ataxia), pruritus and, less commonly, cardiovascular effects.

Analytical Methods and Regulations

Because of the potential hazard to humans, a quick, sensitive, and specific method is needed to determine the presence of marine biotoxins in seafood. The mouse bioassay has been used as the official method in many countries since the 1980s, although the method has poor accuracy, low sample rates, and is time and labor consuming. In addition, the mouse bioassay is not able to differentiate and quantify between individual toxins. With animal ethics in mind, it is highly desirable to develop new analytical methods. Enzyme-linked immunosorbent assay (ELISA) and chromatographic techniques

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have been focused in order to comply with the international regulations. ELISA kits have nevertheless reported many false positive results. Therefore, ELISA is recommended only for screening tests. In 2011, the EU established Commission Regulation (EU) No 15/2011 implementing the liquid chromatography coupled to tandem mass spectrometry (LC/MS/MS) technique as the confirmative method. At present, development of a method to identify marine biotoxins using LC/MS/MS remains slow because there are no certified standards covering all parent and metabolized compounds.

To ensure human safety, the EU and Codex have set marine biotoxin regulatory limits, see Table 1 on p. 33. These limits are defined in terms of toxic equivalency (TEQs), which provides the information about the mixture of toxins and their analogs within the same group. To obtain TEQs, the mass of each toxin found in the mixture is multiplied by its toxic equivalence factor. These individual calculations are then added together and finally reported as total toxicity-weighed mass.

Monitoring Programs

Historically, marine biotoxins were limited to geographic areas where specific algae and host organisms were found. The sources and locations of outbreaks in recent decades are illustrated in Table 2. Outbreaks are now occurring more frequently due to the movement of harmful algae to other areas by international seafood trading, increased consumption, and tourism. Prevention is the best way to manage the risk of potentially serious seafood poisoning. Thus, the major points of monitoring and management programs often include the following elements:

1. Environmental observations of plankton, fish kills, and animal behaviors;
2. Regular sampling of plankton, fish, and shellfish;
3. Analysis of the samples of water and animals for presence and quantification of harmful algae and toxicity of shellfish;
4. Evaluation of the results;
5. Dissemination of information and implementation of regulatory action; and
6. Action plan or mitigation measures.

Each country should develop its own monitoring program and identify one or several agencies from industry, fishermen, or private consultants to verify its effectiveness. Reliable monitoring programs protect public health, minimize product losses, and reduce the costs of clinical treatment and investigation.

Table 2: Marine biotoxins, their source organisms, and the areas where their presence has been revealed.

Toxin	Food Sources	Location of Reported Outbreaks
Saxitoxin (STXs)	Clams, mussels, oysters, cockles, gastropods, scallops, whelks, lobsters, copepods, crabs, fish	Global distribution in temperate to tropical waters
Brevetoxins (PbTxs)	Oyster, clams, mussels, cockles, whelks	Gulf of Mexico, southern Atlantic coast of the US, Gulf of Florida, New Zealand
Domoic acid	Shellfish	Northeast and Northwest coasts of North America
Okadaic acid, dinophysistoxin (DTXs), yessotoxins (YTXs), and pectenotoxins (PTXs)	Mussels, scallops, clams, gastropods	Japan, Southeast Asia, Scandinavia, Western Europe, Chile, New Zealand, Canada
Azaspiracids (AZAs)	Mussels, oyster	Ireland, the Netherlands, Europe
Ciguatoxins (CTXs)	Fish	Tropical and subtropical areas of Caribbean Sea, the Indian Ocean, and the Pacific Ocean

Processing for Detoxification

Because the mechanisms of natural detoxification occur slowly in most shellfish, methods to quicken detoxification help to reduce seafood industry losses. Currently, there are two groups of detoxification techniques for shellfish:

1. Using temperature, salinity stress, ozonation, transplantation, and other methods that accelerate the rate of detoxification; and
2. Removing the toxic tissue and organ of shellfish.

Evisceration alone is not enough when the DA level is very high. The options of combining evisceration with thermal processing or freezing could be used in such cases. Today, the EU has approved procedures for bivalve detoxification for ASP, PSP, and DSP. ■

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REFERENCES FURNISHED UPON REQUEST

Engineering Defensibility in Food Labs

Laboratories' findings must be based on proven processes and robust supporting data

BY **TRISH MEEK**

Few consumers realize how many data bytes go into what they bite. Across laboratories worldwide, technicians process hundreds of thousands of samples—from raw ingredients to the finished products shipped to consumers. The data generated is vital to everything from quality control to traceability.

With so much riding on the accuracy and timeliness of data, few in the industry pause to consider data defensibility. But it's as important in food labs as it is in any industry: Scientists stand behind results and the steps taken to generate them. But the requirement that data be defensible shouldn't conflict with constant demands for rapid throughput, efficiency, and greater productivity.

For many in the food industry, a proven pathway to ensure that data is reliable and defensible is to follow guidelines outlined by industry groups or by global standards organizations like ISO. In particular ISO 17025 sets out standards for the management of testing and calibration laboratories, and outlines guidance for the proper calibration of lab equipment and instruments, maintenance schedules, user training, etc. Adherence to a globally accepted set of standards like ISO is a first step for many labs in pursuit of defensible data. But while this standard has been in place for more than 15 years, compliance hasn't always been easy: Setting up to comply with the standard, especially in a lab that still relies on paper records, is challenging.

The Importance of Data Management

Depending on the food produced, a single laboratory may be responsible for hundreds of tests each week. And no test is just a test; it's the sum of many parts, from the information about where the sample originated to the maintenance records of the instrument used to conduct the test and the technician's training history. The data accompanying a single test is significant, and all of it is equally important in a paradigm of defensibility.

Historically, defending data has been onerous. In the case of a disputed result, lab employees would painstakingly collect and aggregate data from multiple sources, including handwritten notes from fellow technicians. It's not uncommon for technicians to spend a quarter of their productive time simply collecting data to defend a result. Sure, the effort is vital given that public health could be at risk, but these are still hours that could be better spent on activities that are tied to top-line business growth, not time-consuming manual activities, even for something as important as quality assurance or regulatory compliance. Defending data is hard, but it's also not optional.

Like nearly every industry, the food industry is being transformed by technology. And nowhere is this truer than in the lab and with software. In the age of "big data," comprehensive data management software is a big deal, and it is one reason that labs are finding it's easier and less time-consuming to defend their data. Defending may not be as hard after all.

Laboratory information management systems (LIMS) have been around in food safety and quality labs for years. And while the legacy of LIMS may be basic sample management and data reporting, today the capabilities are much more far-reaching across an enterprise: The lab is still where the LIMS sits, but it integrates with data in material requirements planning, enterprise resource planning, and other enterprise systems in ways that enable unprecedented visibility and, most

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important here, rapid, comprehensive and highly efficient defensibility.

Food manufacturers are concerned with physical, biological, and chemical contaminants. In the case of chemical contaminants, many analytical techniques exist to quantify known chemical contaminants in complex food matrices at very low levels, as is often required by regulation. More advanced instruments and techniques can also be used to identify unexpected chemical contaminants such as advanced agrochemicals, pesticides, and veterinary drugs.

Today it's not uncommon for a food lab to use complex workflows that feature mass spectrometry (MS) and gas chromatography (GC) working in tandem to dramatically increase selectivity and sensitivity. And the more complex the workflow, the more reasons to automate the workflow and integrate the lab's instruments with the LIMS, allowing data defensibility to rest in an automated process, and eliminating the errors that can result from manual data handling.

Case Study: Strawberry Jam and GC-MS/MS

For pesticides, many regulations set maximum residue levels (MRLs) at extremely low levels. Many of these MRLs are set at a default value of 0.01 milligram (mg)/kilogram (kg), which is the typical limit of determination of routine analytical methods. This means that some laboratories must test a wide array of foods for a large number of pesticides at concentrations at or below 0.01 mg/kg, doing so with low costs and fast turnaround times.

So let's say that you wanted to test strawberry jam for pesticides. Once you extract the sample and prepare it according to a detailed sample prep workflow, you'd inject it into a GC-MS/MS system and begin your analysis. This is certainly an over-simplified anecdote, but the point isn't to discuss the merits of using GC-MS/MS to analyze complex food matrices. This example merely illustrates how much variability there is in the food testing process. Complex instruments, consumables, technicians, samples, etc.—all part of an eventual defensibility exercise.

So knowing that defensibility is both a requirement and a challenge, what's a forward-thinking lab to do? Engineer defensibility into their processes, of course. But that's easier said than done. Unless, of course, data is already collected and managed in a disciplined fashion. Even better, so much of the larger data collection process has already been automated thanks to LIMS, so all that's required when defending a result is a few relatively easy steps.

The Variables

At a high level, labs must address two main areas: technical quality—including consumable integrity and instrument maintenance and calibration—and staff performance. And much can "go wrong" in these areas if discipline is lacking.

1. Technical quality. Technical quality data includes everything involved with producing an accurate result from an instrument. This presumes flawless staff execution and strict adherence to standard operating procedures (SOPs).

For the strawberry jam analysis above, relevant technical quality data would include reference material certificates, records of approved suppliers, maintenance records, and more. Seems straightforward until one imagines how many times an experiment like this takes place across a busy food lab. The only way to ensure that no misstep compromises a final result is to capture everything within a LIMS as it happens.

Suppliers. From stock solutions to carrier gases, what comes into a lab could affect a result as much as what happens inside the lab. But labs can't afford to test each shipment of consumables, so they often rely on "approved" suppliers that have earned a reputation for—or can document—quality.

But to defend a result, a technician must use consumables from those pre-approved suppliers. And a LIMS can ensure that they do so on every run. Barcoded materials can be tracked as they arrive, associating them with each supplier and linking the instrument running the test and the materials used to do so. During defense of a test result, a technician need only verify within the LIMS that all consumables originated from approved suppliers. If so, consumables are unlikely to be the fail point.

Consumable quality. The origin of a consumable only tells part of the story. Consumables can, after all, go out of specification during storage or use. The LIMS is indispensable here as well: Lab administrators can configure the system to automatically alert staff when a periodic check is required. This capability significant reduces the likelihood that staff will inadvertently use an out-of-specification consumable that would make the test result indefensible.

Instrument maintenance and calibration. Routine maintenance and workflow-related calibration play an important role in defensibility. And keeping track of what was done, when, and by who is time-consuming and error-prone. But not with a LIMS. Lab managers can organize and retrieve maintenance and calibration records by instrument, time period, and even staff member, and they can proactively set alerts to ensure maintenance occurs on a pre-defined schedule.

For calibrations, the LIMS can easily track reference materials as it tracks the data from the calibrations. If there is an issue with a reference material or an out-of-specification instrument, this will be quickly revealed during the gathering of defensibility data.

2. Staff performance. Human error is just as troublesome in the lab as instrument error. Fortunately, the LIMS is designed to help here as well, addressing issues that arise in each of three broad categories: training, process, and data management. Labs should be able to document adherence to policies and procedures across each of these categories.

Staff training. Training is an important function in any food lab. New staff may be unfamiliar with new instruments or workflows and existing staff are confronted with constant change. Training is dynamic enough to warrant greater discipline and rigorous documentation. And whenever discipline and rigor are required, a LIMS is a wise choice. And this is especially true in a laboratory environment where training and certifications can be different instrument to instrument and process to process. Something as simple as a lapsed certification on a GC- MS/MS instrument can be all it takes to negate a test result and cause a costly production slowdown.

Process quality assurance. Workflows are fundamental to laboratory productivity and quality. There are no shortcuts and variation is unacceptable. So what

takes place, by whom, and in what order is critical and must be tracked. A LIMS can help in two ways: it stores the SOPs, automating as much as possible, and it stores the adherence to these SOPs. There is no room for error-causing interpretation. And if a step is missed, the LIMS records that misstep in real-time, perhaps preventing a future indefensible result before it its memorialized as a record of failure.

For labs looking to engineer defensibility into the process, it's almost possible to monitor process quality in real time—the LIMS is constantly looking for exceptions that violate the rule. And it doesn't matter how many different processes and rules are in place, the LIMS is adaptable and can store as many SOPs as a food lab has tests and results to defend.

Data entry and transcription. Manual data entry errors are a well-documented cause for data indefensibility. Even when processes are entirely automated, just a single—even minor—error can cause a bad result downstream. With a LIMS, however, nearly every step can be automated and the resulting data integrated, even from instruments from different vendors. For labs that aspire to engineer defensibility into their processes, there's no question that a LIMS can be the system of record for "designing out" manual entry errors and using automation to close the loop on unintended transcription or other errors.

Visibility Leads to Defensibility

Whether a food safety lab is analyzing complex matrices with GC-MS/MS or using high-performance liquid chromatography to analyze carbohydrates in foods and beverages, there are many fail points. And without a way to ascertain where a result went wrong, it's nearly impossible to defend it.

By engineering defensibility into the process, a lab can take a proactive stance. Upfront work may be required, but the long-term savings in time, aggravation, and cost are immeasurable. And with increasing oversight necessary, thanks to the Food Safety Modernization Act and even stricter European Union regulations, manufacturers will require even more visibility into production processes and related quality assurance and control procedures.

Defensibility is part of working in a lab. And with tougher oversight and the need to defend brands against costly breaches and recalls, the demand will certainly grow. But there is an answer, and a LIMS is the means to achieve it—settle for nothing less than complete visibility. Instruments, consumables, and workflows are among the many parts of a dynamic whole, and once the interrelationships are reconciled it's possible to engineer in defensibility so that it's not an extra burden but instead is an extra measure of protection. ■

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Events

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A Timesaving Approach to Sample Prep

The introduction of a simplified liquid extraction solution to food safety analysis can improve results and drastically reduce sample preparation time | BY **ERICA PIKE**

Image 1: Initial sample prior to cleanup by SLE. At left, coffee with 2% ammonium hydroxide. At right, control ground coffee.

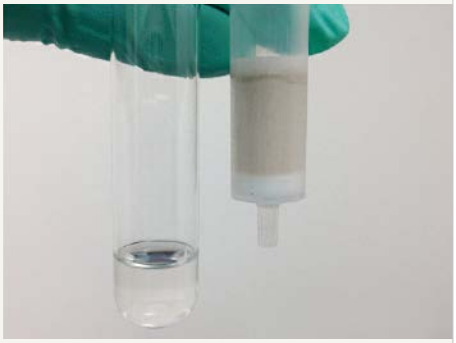

Image 2: Sample after cleanup by SLE. At left, clean sample after extraction. At right, Novum SLE 6 cc tube after extraction.

PHENOMENEX

Food safety is a growing global concern; in fact the food safety testing industry is estimated to reach $15 billion by 2019. While a large portion of this market involves pathogen testing, contaminant testing by techniques such as gas chromatography, high-performance liquid chromatography, and liquid chromatography coupled to tandem mass spectrometry is a growing sector because these techniques provide rapid results and allow analysts to detect and quantify contaminants at extremely low concentrations. While the actual chromatographic analysis is a rapid procedure, samples must be properly pretreated prior to analysis, which can add significant time requirements. As concerns over food safety grow, laboratories must process their samples as quickly as possible, making it extremely important to determine the quickest and most effective sample preparation technique.

There are many sample preparation techniques available to food safety analysts, each of which has its pros and cons. The most effective sample preparation technique is perhaps solid phase extraction (SPE) because it results in extremely clean, concentrated samples; however this technique requires a significant amount of method development time. A more popular technique in the industry is to perform a liquid-liquid extraction (LLE). LLE is fairly quick, does not require as much method development time as SPE, and produces a rather clean sample. To perform LLE, the food sample is first homogenized into a liquid form. Once liquid, the food sample is mixed with a water-immiscible organic solvent by shaking the two solvents in a flask or separatory funnel. During the shaking process, target analytes partition out of the aqueous sample and into the water-immiscible solvent, leaving behind interferences such as lipids, proteins, and salts. The water-immiscible solvent can then be collected by manually separating this layer from the aqueous layer. While this procedure is rather easy to perform, it does introduce challenges such as analyte loss due to emulsions, or bubbles, that can form at the interface of the two liquid phases as well as incomplete collection of the water-immiscible layer during the liquid separation process. These challenges also make the technique difficult to automate, which can eliminate the ability to perform high-throughput sample processing.

Supported liquid extraction (SLE) has become a popular means to avoid the challenges associated with LLE in bioanalytical laboratories; however this technique has not yet been rapidly adopted in the food safety industry. The technique traditionally relies on diatomaceous earth to provide a solid support on which a liquid separation can be performed. Aqueous-based sample is loaded onto the sorbent, which acts like a sponge to distribute the sample across the surface and inside the pores of the sorbent. Water-immiscible solvent is then added to the sorbent and the two liquid phases interact, allowing target analytes to partition into the water-immiscible solvent, which then drips out of the sorbent and into a collection vessel. This technique eliminates the formation of emulsions and the need to manually separate liquid phases. In addition to the ease of use over LLE, SLE can also be automated, which provides further timesavings, particularly for high-throughput laboratories. Traditional SLE products are packed with diatomaceous earth which is a natural product made up of fossilized diatoms. The material can be found in many different mines across the world, and variances in the product can occur if it is mined from multiple locations. To eliminate the potential challenges such as consistency

Table 1: Recovery and % CV of acrylamide.

Sample ID	Ground coffee (100 ng/mL)	Instant coffee (200 ng/mL)
Mean of area ratio	1.89	3.75
STDV	0.01	0.06
CV (%)	0.78	1.61
Absolute Recovery (%)	94.9	92.8
n=	6	6

PHENOMENEX

and performance variances, a synthetic SLE sorbent has recently been engineered by Phenomenex—Novum SLE. With a synthetic SLE sorbent, scientists can expect consistent results from batch to batch due to the stringent manufacturing and QC processes behind the lab-engineered product. This consistency and reliability is important when analyzing low-level contaminants such as hazardous compounds in food.

To test the effectiveness of the new, synthetic SLE sorbent in a food safety testing setting, acrylamide was extracted from both ground coffee and instant coffee.

SLE Extraction Protocol

1. Coffee pretreatment:
Ground coffee, 40 milligrams (mg)/milliliter (mL)

- 60 grams of ground coffee was percolated with 1,500 mL of boiling water

Instant coffee, 8 mg/mL

- 2 grams of instant coffee was dissolved in 250 mL of boiling water

Coffee was allowed to reach room temperature and was then spiked with acrylamide to reach 100 nanogram (ng)/mL (ground coffee) and 200 ng/mL (instant coffee) by adding 20 microliter (µL) acrylamide-$^{13}C_3$ (4 microgram/mL in water) to 800 µL of the prepared coffee. The 150 µL of 2 percent ammonium hydroxide in water was added to the spiked samples that were then vortexed for 30 seconds.

2. Load the pretreated sample onto a 6cc SLE tube.

3. Apply 5 inch Hg vacuum for 5 to 10 seconds to initiate flow into the sorbent.

4. Wait 5 minutes.

5. Load 2x 2.5 mL ethyl acetate/tetrahydrofuran (1:1) and collect under gravity in a collection tube that contains 10 µL ethylene glycol.

6. Apply 5 inch Hg vacuum for 20 to 30 seconds to complete elution.

7. Dry down and reconstitute in water.

After extraction there was an immediate visual difference between the initial sample (see Image 1, p. 38) and the clean sample (see Image 2, p. 38). The resulting clean sample was then analyzed by LC/MS/MS, which resulted in acrylamide recoveries of 94.9 percent from the ground coffee and 92.8 percent from the instant coffee, indicating that the SLE cleanup was not only effective at removing interferences but was also resulted in excellent analyte recoveries. In addition to high recoveries, the method produced % CV values of 0.78 (ground coffee) and 1.61 (instant coffee), which suggests that the extraction is also reproducible (see Table 1, p. 38).

> This technique eliminates the formation of emulsions and the need to manually separate liquid phases.

As the food safety industry continues to grow and monitor an increasing list of contaminants, testing laboratories must find effective and reliable ways to analyze a variety of food samples. Sample preparation is crucial when working with food samples because of the many complex components within the sample; however this is perhaps the most time-consuming step of the analytical process. The introduction of SLE to food safety testing is providing labs with a rapid yet clean solution to sample preparation that is not only consistent and reliable but can also be automated for further timesavings. ■

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Events

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Environmental Monitoring in Microbiological Labs

Similar to food processing facilities, laboratories also require environmental monitoring programs in order to ensure quality end results | BY **VIRGINIA DEIBEL, PHD** AND **VIDYA SRIDHAR, PHD**

It does not seem right that food production plants work so hard taking multiple samples of various types of surfaces, at all times of the day, looking to verify the efficacy of good manufacturing practices and sanitation protocols. The laboratory appears to have the easy part, just testing the samples, seemingly unaware of the how slow the hours pass waiting for results, the relief when they are in-specification, or the panic when they are not. It must be nice to be a laboratory! Well, not so fast. Lab personnel work through the same processes for the same reasons because similar protocols are followed. Laboratories will often carry out environmental testing to ask: Are the good laboratory practices (GLPs) followed by the lab staff and management effective? Are the cleaning and sanitation practices effective? Has there been cross-contamination within the laboratory?

The laboratory environmental monitoring programs (EMP), as in a plant, will vary according to the predominant assays performed, lab areas, traffic patterns, air flow, equipment conditions, and even the season. Careful consideration is made in the development of the program so that it meets the needs of the individual laboratory, while covering the key components that every lab should follow. As those in a food production environment will see, an EMP followed by an in-house or a third-party contract lab adhere to similar steps to ensure that the data generated are accurate, reproducible, and dependable.

Key Components

Environmental monitoring zones and site list selection. In any EMP, it is critical to define what constitutes highest risk areas, such as sample contact areas (zone 1), to lower risk areas, such as floors and walls (zone 3). The importance of developing a thorough site list and establishing zones cannot be underestimated. Each lab area where samples are logged-in/staged, media prepared, dishes washed, samples incubated, assays conducted, plates read, and materials autoclaved must have locations represented within the environmental monitoring site list.

If the trending data suggests that some zone 3 sites have been identified as "hot spots," then site lists should represent this zone in proportions related to the data. The site list should be reviewed on a periodic basis to account for added or removed equipment, new test methods, substantive construction or site modifications, and any facility issue.

Table 1: Environmental zones for monitoring in a microbiological testing lab.

Zone 1: Any surface where a sample has direct contact, i.e., pipette tip, mixing vessel
Zone 2: Adjacent to sample contact, i.e., lab coat, stomacher paddles/controls, centrifuge, handles, laminar flow hoods and bio-safety cabinets, scale, control panels
Zone 3: Equipment and infrastructure where samples are exposed, i.e., cabinets, carts, hand wash sinks, floor/floor mat

Since each lab may have different processing areas, equipment, and utensils, site lists may be unique for each lab even if they are under the same ownership. However, the principle of including sites within each critical lab area, representing all zones, remains across all labs. Table 1 provides a general overview of environmental zones in a lab.

Assays selected. The assays selected for each sample are those that are conducted on samples. For example, if incoming lab samples are tested for *Listeria* spp., *Salmonella*, coliforms, *E.coli,* and coagulase-positive *Staphylococcus* then those are the assays to be included in an EMP. Whatever organisms are tested, the same methods that the lab is asked to run are to be used for the EMP. When yeast and mold are tested, see Air Monitoring section below.

Sampling modalities include swab, sponge, amplicon, and air sampling. Amplicon sampling withstanding, samples are either categorized as indicator or specific organism.

Indicator organisms are used to assess the overall microbial load of a sample site. Aerobic plate count (APC) measures the number of bacteria that grow aerobically. Results are obtained in 48 hours. An APC assay can assess the efficacy of cleaning and sanitization when sponges are taken immediately after the event. When the results are out of specification, cleaning/sanitation procedures should be reviewed and revised. When areas such as door handles, carts, pipettor handles, or control panels are swabbed between cleaning and sanitation, the results can be used to provide an indication of not only their current microbial load, but how often the sites should be cleaned/sanitized. In this regard, close monitoring, or tracking, of data is a key function of environmental monitoring programs. APC, coliforms, and *Enterobacteriaceae* are examples of indicator organisms.

One note about indicator samples is they may be tested to assess cleaning/sanitation efficacy on a more frequent basis or at specific times.

Air monitoring. Just as in a production environment, laboratory air quality can be monitored when yeast and mold is tested. Mold spores, in particular, can be spread via air currents. Many times, yeast and mold counts have seasonal variations. Summer months may show higher counts than winter, especially in states that experience winter freezes. Increased counts may also indicate water leaks, clogged air filters or doors left open. There are a number of methods for monitoring air quality. The use of an air sampler that draws air and impacts it onto a petri dish is a valuable tool. Alternatively, passive air monitoring wherein settling plates are used is a common, inexpensive method of air collection—

media is exposed to operational air for a pre-determined amount of time. During air monitoring, normal operations should be taking place.

Sampling frequency. The frequency depends on the number of sites and how often the lab wants each site sampled. For most labs, at least weekly sampling is a good place to start. Sampling should take place on different days of the week to account for differing sample loads and activities. Table 2 outlines an example of a sampling frequency program. When samples are selected, they should be randomized by using a random number generator such that all sites have an equal chance of selection. Keep in mind that with randomized sampling, some samples may be tested two or more times and some may not be tested at all in a given timeframe.

Setting specifications. For any program, setting specifications is not an exact science. Zone 1 post-sanitation results should be less than 10 colony-forming unit/sponge or negative depending on the type of assay. Zone 2 and 3 specifications may be set initially and then change depending on baseline data that is collected over multiple months. Tracking and trending consecutive data from six to 12 months is a good rule-of-thumb to set specifications. After this period of time, the lab management reassesses and possibly revises specifications. Table 3 provides examples of specifications for zones 1 to 3.

Data collection and review. Each month, the site list and results should be reviewed by lab management to ensure sampling is conducted as per the SOP, that out-of-specification results have been addressed, and that corrective actions were effective and verified. This review also allows identification of developing trends. All data should be reviewed in a historical context and relevant corrective/preventive actions should be included in the monthly review.

Corrective actions. If presumptive and/or out-of-specification results are observed, involvement of varied management levels provides a diversity of perspectives and ideas for corrective activities.

Corrective actions are activities that are conducted as soon as possible after result notification. For example, the sample site and surrounding area will be cleaned and sanitized before the close of business on the day the results are observed. After cleaning and sanitizing, the sample site(s) are to be sampled to verify the efficacy of the cleaning/sanitizing event. Sampling of the site will continue each day until three consecutive in-specification results are obtained. When this qualification is met, the sample is returned to the site list for routine monitoring. These samples are to be taken after cleaning and sanitation of the site has been performed. If any of these samples are out-of-specification an investigation should be launched.

The investigative process can be initiated for an out-of-specification result or when a client result is positive to verify there was no cross-contamination event. A team will determine sites of additional samples and review past records. The investigative samples, or vector samples, should be collected in a 360-degree radius, if possible, from the initial out-of-specification. Vector samples may include locations adjacent, under, and above the initial site. In addition to vector sampling, the investigative team observes the site and lab operations. The team is looking at the process, lab environment, equipment, and utensils. Any abnormalities or adjustments made should be documented.

Table 2: Sampling frequency for zones and organisms.

Zone	Check of	Number of Sites	Organism(s)	Frequency
1	Sanitation	5	*Enterobacteriacae*	Weekly
	Sanitation		Aerobic Plate Count (APC)	
	Cross-contamination		Coagulase positive *Staphylococci*	
	Cross-contamination	5	*Salmonella*	
	Cross-contamination		*Listeria spp.*	
	Cross-contamination	2	Amplicon	
	Air quality	2	Yeast and mold	
2	Sanitation	3	*Enterobacteriacae*	
	Cross-contamination		Coagulase positive *Staphylococci*	
	Cross-contamination	3	*Salmonella*	
	Cross-contamination		*Listeria spp.*	
3	Cross-contamination	2	*Salmonella*	
	Cross-contamination		*Listeria spp.*	

Table 3: Specifications for microorganisms for zones 1-3.

Zone	Organism	Specification (per sponge/ swab)
1	*Enterobacteriacae*	<10 CFU
	Aerobic Plate Count	<10 CFU
	Coagulase positive *Staphylococci*	<10 CFU
	Salmonella	Negative
	Listeria spp.	
	Other pathogen assay	
	Yeast and mold air plate	<15 CFU/ 15 minutes
2	*Enterobacteriacae*	<10 CFU
	Coagulase positive *Staphylococci*	<10 CFU
	Salmonella	Negative
	Listeria spp.	
3	*Salmonella*	Negative
	Listeria spp.	

Summary

An effective laboratory EMP will help verify cleaning and sanitation effectiveness, employee practices, and air quality in the laboratory. The program also incorporates direction when there is an out-of-specification result and the appropriate investigative process. These practices ensure accountability and quality results that clientele can depend on. ■

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REFERENCES FURNISHED UPON REQUEST

Even with a steady stream of high-mast forklifts accessing the GSF freezer room, this high-speed door on 16-ft. high doorway can close in under two seconds.

At the Palermo's Pizza plant in Milwaukee, the high speed and tight doorway seal protects product quality while enabling them to save about eight tons of refrigerant a year.

Traffic Doors and Cold Storage

High-speed doors can beat the clock while respecting the thermometer to protect food quality where product is handled or processed

BY **MICHAEL WATKINS**

There really are no perfect choices.

Take the doors used in food processing/handling plants for traffic going in and out of chilled and frozen areas for storage and production. At all of these facilities vehicles go through doorways hundreds if not thousands of times a day to meet split-second schedules. At the same time, temperature differentials can run 35 degrees Fahrenheit or more, and there needs to be protection against heat transmission through these 80 foot (ft)^2 or larger openings, threatening both energy bills and product quality.

Plants and DCs regard getting product rapidly from the receiving dock to the shipping dock as crucial to profitability. Also important is maintaining proper temperatures to protect food quality where product is handled or processed. Not only is the desired flavor and mouth feel threatened but also product that is warmer than it should be promotes the growth of bacteria and other microorganism contaminants.

Safe at Faster Speeds

Doors play a key role in protecting the low-temp environment—if specified and used properly. In the storage and handling areas maximum temperatures for vegetables are 55 degrees Fahrenheit, dairy products are 34 degrees Fahrenheit, meat at 28 degrees Fahrenheit, and ice-cream at -10 degrees Fahrenheit. Waiting outside the processing or storage room can be temperatures that are 30 degrees Fahrenheit or higher.

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At the GSF DC, 52 dock doors receives product and keeps 460 McDonald's restaurants supplied with everything from buns to burger patties.

That warmer air can be transmitted through walls and door panels. As for walls, the higher the R-value for the insulation the better. But is that necessarily true for doors?

Bear in mind that doors have to get out of the way of traffic. So here is the dilemma for facility food processing/handling facility managers—do you cover the doorway with a thick panel door and slow down material handling, or compromise the environment to enable fast traffic flow? Not only is product put at risk if the temperature rises, but to maintain spec temperatures chillers have to work harder, start up more often, and use more energy while shortening their performance life.

Recent research from the Door and Access System Manufacturers Association (DASMA) provides some help in making this choice. The study, "High-Speed Doors and Thermal Performance," finds that today's industrial and commercial buildings can deliver high door speed while at the same time save energy, depending on doorway factors.

The DASMA research took into consideration common U-factor, air leakage, and motor horsepower values in a comparison of high-speed doors to conventionally operating insulated doors. Turns out high-speed doors become more energy efficient when cycled 55 or more times per day, according to this analysis. As you may know, in a busy facility doors can be cycled hundreds if not thousands of times a day.

While 55 cycles is the minimum, high-speed doors are typically specified for applications requiring well over hundreds of cycles daily. Thus, the doors studied demonstrate superior overall energy efficiency when meeting the demand for high-cycle operation in a building.

This new approach views the doors as dynamic parts of the building. High-speed doors, in addition to providing rapid access, also contribute to the efficiency of a low temp operation through dynamic thermal performance characteristics when the door is not closed.

High-speed doors are excellent at controlling air exchange—the air flowing through an opening when a door is not fully closed. In fact, when taking thermal transmittance (i.e. U-factor), air leakage, and door power usage into consideration, air exchange can be the most significant part of the total energy loss for a door, depending on the application.

With this in mind, the door manufacturer should be able to supply the opening and closing speeds, as well as U-factor and air leakage performance values to make a more accurate assessment of doorway need based on actual or projected usage.

Case In Point

Here is an example of these considerations in action. The recently completed Golden State Foods (GSF) 3PL outside of Chicago supplies product to the McDonald's restaurants throughout northern Illinois and Indiana. Through the years, McDonald's has brought diversity to their menu and now salads and fruit are joining the chain's traditional burgers and fries. These changes mean that GSF offers frozen and chilled storage, and to handle this product they have opted to install high-speed doors on their low-temp areas.

The operation has 23,400 ft.^{2} of freezer space with a 40-ft. high ceiling at -5 degrees Fahrenheit temperature. A minimal footprint on the floor means a minimized ceiling, reducing the amount of heat loss through the roof.

Consequently the reduced freezer floor space means fewer doorways cut into the walls for forklift access. For the GSF freezer room, they have four doorways to handle the inventory turns that happen every day and a half.

Because of the high number of daily cycles, the facility opted for the high-speed doors. Though the doors have fabric curtains, the door speed minimizes the exposure of the freezer storage room to the 34 degrees Fahrenheit shipping and receiving docks—a temperature differential of 39 degrees Fahrenheit.

Insulated panels enable the door to retard heat transfer, but do not impede the door's ability to operate at speeds over 100 inches per second. The combination of the door speed and the insulated panel helps the facility save 40 percent of energy and reduce operating time on the refrigeration system for longer system life as well. The facility can maintain storage temperatures to provide the product quality McDonald's demands.

Another issue around solid panel doors is dealing with continual damage. Because of their slow operation coupled with the material handling system's need for speed, the doors can get hit by vehicles, often disabling door operation. With just four openings into the freezer, GSF cannot afford this kind of disruption.

Moreover, a damaged door can leave the freezer product exposed until the repair crew arrives, causing a tremendous loss of cold storage energy. Even if the damage is minor the door can be knocked out of alignment, causing energy-loosing gaps between the panel and the doorframe. As for a high-speed door if a vehicle can somehow hit the panel, the door is designed to self-repair in just moments.

When a high-speed door is closed, the design ensures the doorway is tightly sealed. On the sides, the door guides enclose the vertical edges of the door panel. Brush seals, combined with the idler barrel, seal at the top of the door. The bottom gasket hugs the floor's contours. Cold air has nowhere to go except for the brief time the door is open.

The times are rare when a building component can make an effective contribution towards satisfying multiple needs for a facility. In the case of GSF and other operations, a high-speed door can maximize material handling flow, work towards achieving a net-zero building, all while getting product safely to market. ■

Watkins is vice president, marketing, for Rytec High Performance Doors. Reach him at MWatkins@rytecdoors.com.

Get Into the Cloud

The power of the cloud in harmonizing food safety and quality assurance anywhere and anytime

BY **BARBARA LEVIN**

Food safety and quality assurance (FSQA) issues pose the biggest risk to the brand reputation and financial health of food and beverage companies. Yet, when it comes to daily FSQA operations, industry has struggled with making broad and effective changes. But in the face of regulatory challenges such as the Food Safety Modernization Act, pressure to provide safe, quality products on time and within budgetary key performance indicators (KPIs), heightened consumer awareness of food safety issues, and of course C-suite commitment to protecting market value and brand—a fundamental change in FSQA operations is necessary. This article makes the case that key to this change is leveraging the power of cloud-based food safety technology solutions.

Right Time and Right Technology

When I first came to the food industry as an evangelizer of technology for improving FSQA, I was told, "Food companies don't deploy technology." After much research, it became clear that food companies *did* deploy many software solutions for various corporate functions—supply chain management, procurement, finance, human resources, to name a few. These technologies saved time, saved money, and created operational efficiencies.

What was true, however, was that the FSQA functions within food companies, which logically would seem to be top candidates for the benefits of automation, lagged behind in technology adoption. It is this author's belief that this was due largely to the types of FSQA solutions that were available pre-cloud/pre-mobile—traditional on-premise or "behind the firewall" solutions. FSQA teams aren't sitting at their desks in front of computers. They're in the field doing pre-harvest inspections; on the plant floor monitoring food safety processes; on the road auditing high-risk suppliers; or onsite responding to customer issues. Technology solutions that required users to be at their desks were therefore inefficient. On-premise technologies were also expensive to deploy and maintain, making it difficult to build a business case given low food industry profit margins.

But over the past decade, we've seen this change. Today, many FSQA technology vendors offer cloud-based solutions that can be accessed anywhere, at any time, using mobile devices. And as a result, we're seeing FSQA technology adoption becoming more mainstream.

Affordability of FSQA in the Cloud

Cloud-based technologies are "multi-tenant." This means that there are central applications, built with best-practices functionality, that are shared by all of the companies using the solution—*but every company has its own private, sub-section*—configured for its specific needs. The "tenants" enter the applications with their own secure logins. There's no hardware or software to buy and maintain.

Additionally, when industry drives the need for changes to the applications, all of the tenants receive the enhancements, keeping the systems up-to-date for all. For example, if you are using a cloud-based solution for Global Food Safety Initiative (GFSI) automation and one of the schemes issues a new code version, the vendor would typically update the code and push it out to all companies using that application—eliminating the need for you to spend time and money making these changes.

Common Myths About the Cloud

Myth 1: Cloud-based applications are not as secure as on-premise solutions. The bottom line is that today's cloud-based applications are highly secure. Think about cloud-applications we use every day, such as online banking, where highly sensitive information lives in the cloud. Vendors follow very strict rules about security and offer audits to prove that they meet or exceed standards.

Myth 2: Lack of controls over who sees what. Cloud-based applications are roles-based, meaning you control who sees what. Think about logging into your online banking account, you see your activity and balances, not those of everyone

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else who uses that same application. With cloud-based FSQA apps, you control who sees and does what. You might allow suppliers to login to enter certificate of analysis information, for example, but not allow them to see other data in the system.

Myth 3: You do not own your data in cloud-based applications. You can and should own your data, and this should be in your vendor contract. If you decide to leave a vendor, you will have the right to take your data with you.

Harmonizing FSQA in the Cloud

A comprehensive cloud-based FSQA suite will typically include upstream, internal, and downstream functionality. This might include modules for Supplier Compliance, Food Safety and Quality Management, and Regulatory/GFSI Compliance.

Cloud-based solutions operate on mobile devices and via secure login portals, allowing you to automate and streamline FSQA at all points along your value chain—from anywhere, at any time. They collect and analyze FSQA data at the point of origin: in the field, in the plant, on the road, or at the receiving dock. Information can come in from suppliers, equipment, and labs—and go out to distributors and customers. Workflow engines ensure all tasks—for every plan, across all facilities—are completed. In the cloud, FSQA data is analyzed against specifications in real-time because there's no paper. Alert systems, "food safety smoke alarms in the cloud," if you will, push non-conformance alerts in real-time, facilitating timely corrective and preventive actions (CAPAs).

Regardless of how many facilities, suppliers or customers you have, all FSQA program components and records live in your own central data repository that can be accessed from any computer or mobile device with a web browser. This is where harmonization of FSQA comes in.

All prerequisite programs, good manufacturing practices, standard operating procedures (SOPs), and the like, along with associated forms, live in the central repository. This means that regardless of where an FSQA team member is located, updated forms and specifications are always used.

Quality and operations directors, for example, can access dashboards on tablets anywhere to view and compare status of FSQA across the entire operation.

And there's no more "data rich and information poor." All FSQA data and records are centralized, actionable, and accessible for trending, reporting, continuous improvement, and audit readiness.

Impact on Daily FSQA Operations

There are literally thousands of examples that can demonstrate the impact of cloud-based, mobile technologies on FSQA operations. The following two focus on upstream and production scenarios.

Scenario 1: Going to supplier fields to inspect produce prior to harvesting for packaging at the plant.

Traditional Manual System:

- Inspector goes to field to do visual inspection; records a direct observation non-conformance, such as signs of animal intrusion, on paper forms.
- Goes back to office; faxes forms to FSQA manager or enters into spreadsheets and sends via email along with notations of observed non-conformances.
- When manager receives, he/she sends back a CAPA; if unable to reach manager, or if manager isn't logged into email, it could take hours for this step to happen, and as we know in the food industry, time equals money.
- Inspector returns to field, has CAPA executed, records again on paper, and files forms upon return to office (hoping they can be easily found for audit).

Cloud-Based Mobile Empowered System:

- Inspector goes to fields and records all observations on mobile device form.
- If a non-conformance against a spec is detected during the real-time analysis, an auto-alert is sent to the FSQA manager, who receives a push notification on his or her mobile device, regardless of where he are she is.
- A CAPA is generated in real-time and sent back immediately to the inspector.
- When the CAPA is complete, it's recorded on the mobile form, including before/after digital pictures, and automatically becomes part of the permanent record—accessed on-demand for audits and continuous improvement.

Scenario 2: Plant floor SOP for metal detector calibration prior to production line startup to package bags of cookies.

Traditional Manual System:

- Line supervisor has SOP to calibrate metal detectors on his/her lines by 4:55 a.m. daily prior to materials coming down the line.
- Today, this supervisor calls in sick at last minute; another supervisor is balancing managing multiple lines, and the metal detector SOP "slips through the cracks."
- At noon, the plant manager, reviewing the morning's operations forms, notices the SOP was missed; now all cookies previously packaged must be taken out of the bags and re-run through the metal detectors after proper calibration.
- The packaging materials are wasted and 30 percent of the cookies are broken in the process; KPIs for the day are now off, inventory has to be replaced, and overtime must be paid to ship to the customer on time.

Cloud-Based Mobile Empowered System:

- At 4:40 a.m., all line supervisors receive alert on their mobile tablets with notification that the auto-scheduled SOP is due to be completed by 4:55 a.m.
- At 4:55 a.m., the plant manager and appropriate production supervisor receive Non-Compliance Report (NCR) alerts that the calibration was not entered for a particular line.
- At 5:02 a.m., the production supervisor electronically completes the NCR-CAPA; auto-notification also sent to plant manager that the issue has been successfully resolved.
- The electronic records of the auto-scheduled SOP, the alert, the issuance of the corrective action and the completion of the task are time/date stamped and now part of the permanent record for audit readiness and continuous improvement.
- The problem is corrected before the line start-up, avoiding waste and rework, thereby reducing cost of quality and helping the plant stay within its daily KPIs.

The bottom line? Cloud-based FSQA technologies save time, save money, and create operational efficiencies that harmonize and improve food safety and quality. ■

Levin is the senior vice president of marketing and a co-founder of SafetyChain Software. Reach her at blevin@safetychain.com.

NEW PRODUCTS

Laboratory Homogenizer

The Panther NS3006L is a high-pressure homogenizer, which is a standalone, fully equipped laboratory unit that is designed for continuous operation up to 1,500 bar for limited productions in pilot plants. This compact laboratory homogenizer is ideal for the micronization of dairy products, fruit juices, liquid food, food additives, and ingredients. It is constructed from Super Duplex SS alloy and is fitted with wear-resistant components. The analog pressure gauge has a sanitary design with a built-in pulsation damper. **GEA, 603-606-4060, www.gea.com.**

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The new AccuPoint Advanced ATP Hygiene Monitoring System features an improved sampler chemistry to help produce more consistent results with greater sensitivity—and the ability to be stored at room temperature for up to two weeks. Advanced Data Manager software streamlines the testing process by creating test plans and syncing important data, while keeping a permanent record of hygiene test results. The system also includes an enhanced instrument to produce faster results (less than 20 seconds). **Neogen Corp., 800-234-5333, www.neogen.com.**

Sulfite Detection

MaxSignal Sulfite Assay Kit detects total sulfites in multiple sample types. This enzyme assay uses a rapid aqueous extraction, and an enzymatic reaction that requires only 20 minutes to reach completion. The kit can detect as little as 0.5 ppm of sulfite in aqueous extractions. It provides enough material to perform 50 determinations in a 1 mL cuvette, or 192 determinations in a microtiter plate (plus additional material for controls). **Bioo Scientific, 888-208-2246, www.biooscientific.com.**

Modular Rheometers

The HAAKE MARS (Modular Advanced Rheometer System) 40 and 60 rheometers are equipped with Connect Assist technology, which automatically detects measuring geometry accessories and temperature modules to deliver real-time feedback. Rheometers streamline workflows by offering application packages that bundle the rheometer with task-specific accessories. A two-column modular design allow for easier access for sample preparation with quick-fit accessory connections and measurement setup, including an intuitive display and control panel. **Thermo Fisher Scientific, 800-556-2323, www.thermoscientific.com.**

Noodle Tensile Fixture

TA-NTF Noodle Tensile Fixture for Brookfield's CT3 Texture Analyzer is designed to test the extensibility and tensile breaking strength of noodles, pasta, and other similar food items. The lower and upper grip assemblies are included with the fixture. CT3 Tester operates in both compression and tension modes. A variety of standard probes (cones, cylinders, blades, balls, punches) and fixtures (extrusion cell, shear cell, grips, etc.) are available for a multitude of applications. **Brookfield Engineering Laboratories, 800-628-8139, www.brookfieldengineering.com.**

In Other Product News

InstantLabs partners with **FDA** To commercialize a new *Ictalurid* catfish species identification test as part of a Cooperative Research and Development Agreement.

The AOAC-RI grants a method extension for the **DuPont** BAX System real-time PCR assays for *Listeria* to include validation of a new proprietary enrichment media. The method allows users to perform a single-stage, 20 to 26 hour enrichment in FoodChek Actero Listeria Enrichment Media, followed by rapid processing with the BAX System.

Ecolab receives a 2015 IFT Food Expo Innovation Award for the development of DrySan Duo, an EPA-registered technology providing a no-rinse cleaner and sanitizer for dry- or low-moisture processing environments.

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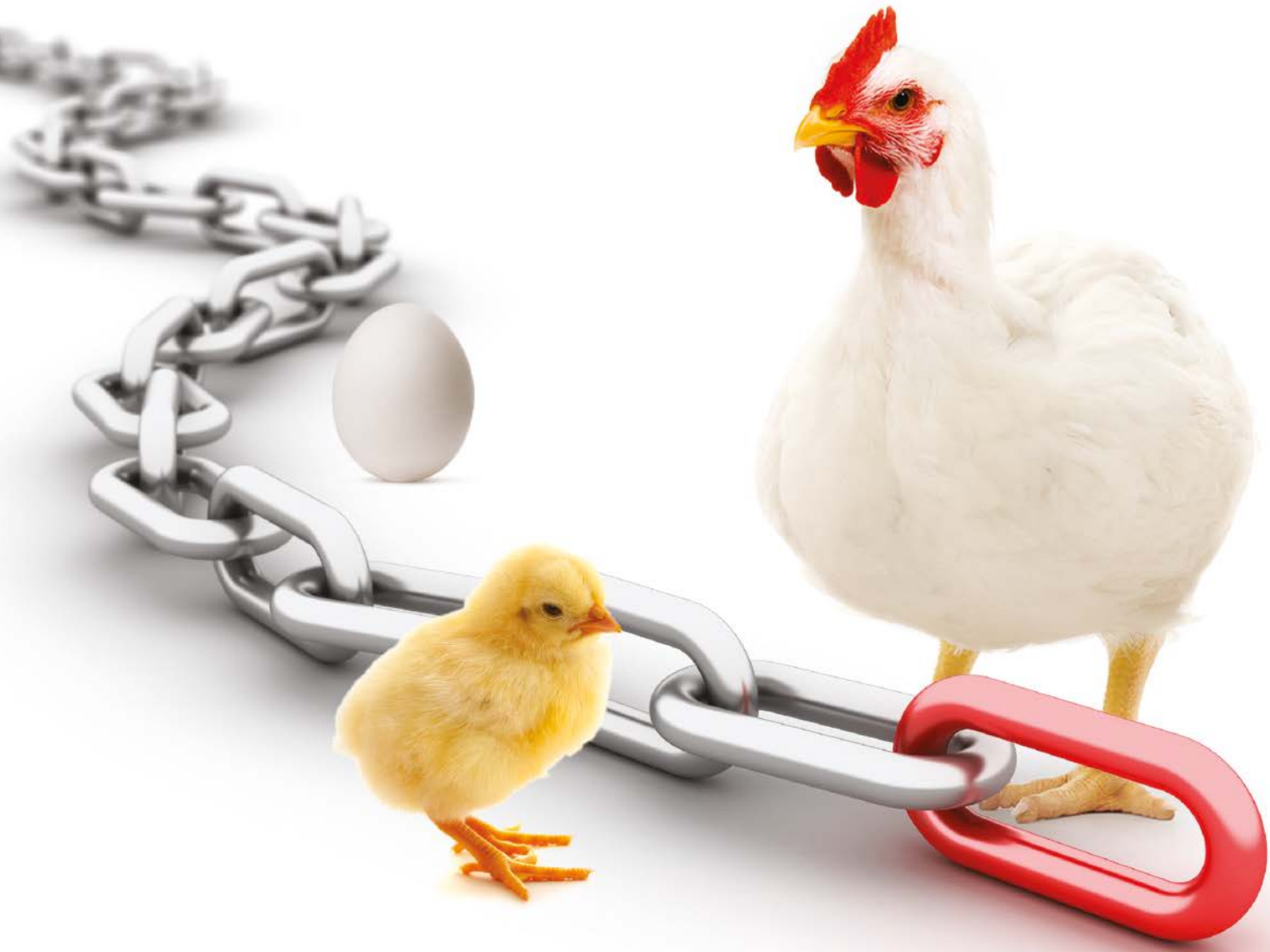

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