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Volume 23 Number 5
OCTOBER / NOVEMBER 2016

Food Quality & Safety

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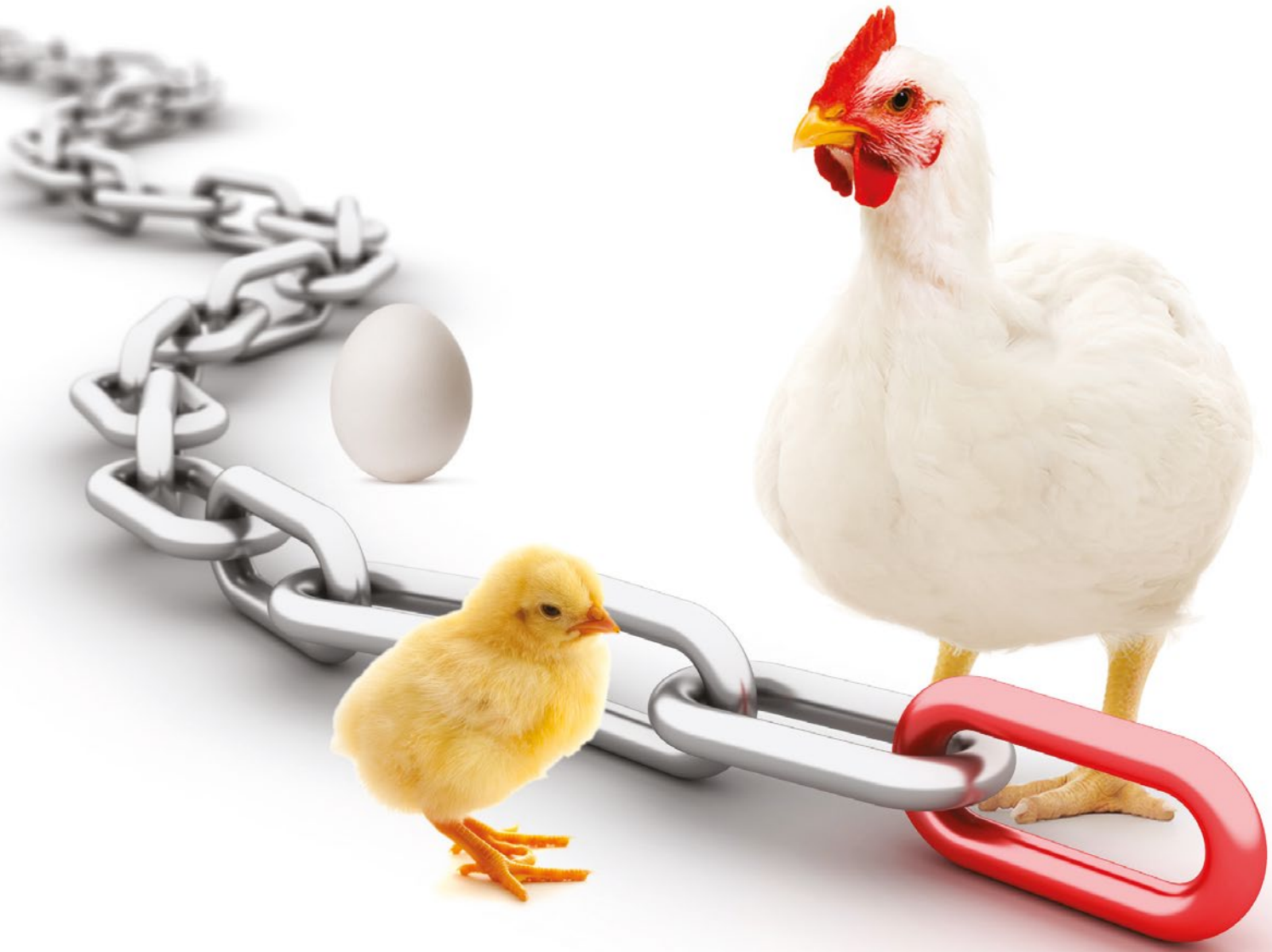

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CORRECTION

The Washington Report article, "Will Food Labels Go Au Naturel?" in the August/September 2016 *Food Quality & Safety* issue incorrectly referenced Urvashi Rangen, PhD, director of Consumer Union's Food Safety & Sustainability Center, as "he" instead of "she."

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From The Editor

Water is a resource that the U.S. has taken for granted for many years. But times are changing.

The safety of our water supply has come into question across the country. The lead-laced water in Flint, Mich., chemical contaminants PFOA and PFOS in Alabama tap water, and water tainted with PFCs in Colorado are just a few of the more recent examples.

Water touches every facet of life, including food security, so it's a bit scary not being able to trust our water sources.

In recognition of the country's growing concerns surrounding water resources and infrastructure, the White House, along with about 150 other institutions, pledged more than $5 billion on March 22, 2016 (World Water Day) to improve the nation's water accessibility and quality. "Water challenges are facing communities and regions across the United States, impacting millions of lives and costing billions of dollars in damages," according to White House statement.

Yet despite these good intentions, new concerns over safe drinking water continue to emerge.

The most recent potential water crisis is centered around the construction of the Dakota Access pipeline near the Standing Rock Sioux Reservation in North Dakota. In addition to destroying sacred lands and burial grounds, crossing the pipeline under the Missouri River means that any oil leaks would contaminate the only water supply for the reservation. Their concerns are not unfounded as the oil industry has a history of pipeline leaks and spills.

The Standing Rock Sioux Tribe and other Indian Nations have been protesting the pipeline since April with meaningful messages of "Protect our water" and "Water is life."

With the help of Earthjustice, the tribe recently filed suit against the Corps of Engineers, saying the Corps violated the Clean Water Act, the National Historic Protection Act, and the National Environmental Policy Act. At press time, a federal appellate court granted an injunction to temporarily halt construction over certain portions of the pipeline as it considers these tribal claims.

With the future of our water supply already in question, can we afford to take a chance in irrevocably contaminating yet another water source?

Marian Zboraj
Editor

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FARM TO FORK SAFETY

EXECUTIVE EDITOR/PUBLISHER Lisa Dionne, ldionne@wiley.com
SENIOR ACCOUNT MANAGER Ken Potuznik, kpotuzni@wiley.com
EDITOR Marian Zboraj, mzboraj@wiley.com
DESIGN Maria Ender, mender@wiley.com
PRODUCTION Claudia Vogel, cvogel@wiley.com
Jörg Stenger, jstenger@wiley.com
Elli Palzer, palzer@wiley.com

Advertising Director
Dan Nicholas
111 River Street
Hoboken, NJ 07030
(716) 587-2181
dnicholas@wiley.com

Sales Office
U.S./Canada/International
Ken Potuznik
29822 N 51st Place, Cave Creek, AZ 85331
(480) 419-1851 • fax (480) 718-7719
kpotuzni@wiley.com

Editorial Office
111 River Street, Hoboken, NJ 07030-5774, USA
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NEWS & NOTES

Guidance for the Labeling of Infant Formula

The Labeling of Infant Formula industry guidance from the U.S. FDA helps infant formula manufacturers and distributors comply with certain labeling requirements. In this guidance, the FDA clarifies requirements pertaining to the following labeling elements: statements of identity, "exempt" infant formula, nutrient content claims, and health claims and qualified health claims. Additional infant formula labeling requirements include directions for preparation and use, pictograms, use-by dates, water statement and symbol, warning statements, and physician's recommendation. It also includes information on general labeling requirements, such as intervening material, foreign language and religious symbols, statements intended for specific religious needs, and allergen statements.

Global Organic Trade Guide

The Organic Trade Association's enhanced online International Organic Trade Resource Guide provides up-to-date market, policy, and trade information on global organic markets available for American organic exporters and importers. It features information for 40 countries and 38 trade regions along with key marketing and policy data on each specific region. From the trade guide's interactive map, users can pick a country and understand the growth and demand for organic products, top retailers and brands, and consumer demographics in that market. Access available at www.globalorganictrade.com.

PMA, United Fresh Joint Working Group on *Lm*

Produce Marketing Association and United Fresh Produce Association are collaborating to address produce-specific challenges surrounding *Listeria monocytogenes*. While both organizations have been actively working with their respective members on individual projects related to reducing the risk of produce-associated foodborne illnesses from *Listeria monocytogenes*, additional areas exist where a joint effort will result in greater efficiency and a more meaningful impact within the fresh produce industry.

Gluten-Free Diet On Rise, Celiac Disease Isn't

As reported by Reuters Health, more people in the U.S. are on gluten-free diets even though the proportion of Americans with celiac disease held steady from 2009 to 2014, according to a new study. Despite the fact that gluten-free diets are not known to provide any health benefits for the general population, some people believe they benefit from going gluten-free, said lead author Dr. Hyunseok Kim, Rutgers New Jersey Medical School in Newark. Researchers used data collected on 22,278 adults and children in the U.S. who were at least 6 years old and had been tested for celiac disease or interviewed about prior diagnoses. About 0.7% of people were diagnosed with celiac disease, and about 1.08% were adhering to a gluten-free diet without being diagnosed with celiac disease. The proportion of people in the U.S. with celiac disease remained stable during the study, the researchers found. However, the popularity of gluten-free diets increased during that same time.

FDA Provides $21.8 Million to States for Produce Safety

The U.S. FDA announces the awarding of a total of $21.8 million to support 42 states in the implementation of the FSMA produce safety rule. Cooperative agreement between the FDA and the states provides awardees with the resources to formulate a multi-year plan to implement a produce safety system and develop and provide education, outreach, and technical assistance. It will help prioritize farming operations covered by the produce safety rule and develop programs to address the specific and unique needs of farming communities.

Business Briefs

Diamond V plans expansion of current manufacturing complex in Cedar Rapids, Iowa to support the increased production of natural, nutritional health products for animals.

Emerson expands global capabilities in fresh food monitoring with acquisitions of **Locus Traxx** and **PakSense**.

Bühler and **Bosch Connected Devices and Solutions** expand their existing R&D partnership to further leverage opportunities of the Internet of Things for food processing industry.

NSF International completes the acquisition of **Euro Consultants Group,** a food safety and quality service company based in Wavre, Belgium.

Washington Report

USDA Begins Crafting Rules for Mandatory GMO Labels

Critics complain new law is riddled with exemptions and loopholes | BY **TED AGRES**

Only days after President Obama signed into law the first federal legislation requiring food manufacturers to disclose GMO ingredients on packaged food labels, USDA's Agricultural Marketing Service (ARS) announced it would begin the process of drafting rules to implement the measure. The controversial bill has reinvigorated battles between consumer groups and food manufacturers, triggered a bitter rift within the organic food industry, and puts USDA, which is charged with implementing the law, into potential conflict with FDA, which has sole statutory authority over food labeling.

"USDA has established a working group to develop a timeline for rulemaking and to ensure an open and transparent process for effectively establishing this new program, which will increase consumer confidence and understanding of the foods they buy, and avoid uncertainty for food companies and farmers," the agency announced on a new website devoted to the issue. "We are committed to providing multiple opportunities for engagement." The Foreign Agricultural Service and the Food Safety and Inspection Service are participating in the working group. The USDA must create the regulations within two years.

Obama signed the National Bioengineered Food Disclosure Law (PL 114-216) on July 29, 2016 after the Senate and House had passed the measure (S 764) earlier that month. The law supersedes and bars any similar state laws, permits companies to use an electronic link, such as a QR code, for disclosure rather than a text label, and carries no penalties for non-compliance. Many consumer, environmental, and anti-GMO groups contend the law is too lax, and some accused lawmakers of being in the pocket of Monsanto and in collusion with big agribusiness.

The short, 14-page bill bypassed typical congressional committee hearings and legislative markup, having been fast-tracked by Senate Agriculture Committee Chairman Pat Roberts (R-KS) and ranking member Debbie Stabenow (D-MI). They did so, in part, because Vermont's GMO label disclosure law, the nation's first, was set to go into effect on July 1, 2016 and many in the food industry, including the Grocery Manufacturers Association (GMA), had warned of potential disruptions from differing requirements mandated by disparate state laws.

The federal legislation "will open a new era for transparency in ingredient information for consumers by requiring disclosure of genetically engineered ingredients for families in every state across the nation," says Pamela G. Bailey, GMA president and CEO. "Its consistent national standard is far better than a costly and confusing patchwork of different state labeling."

The new legislation pre-empts Vermont's mandatory on-package labeling law, which she says "already has left consumers in the state with fewer products on the shelves and higher compliance costs for small businesses."

Prior to the Senate vote, Stabenow said "this bipartisan bill ensures that consumers and families throughout the United States will have access, for the first time ever, to information about their food through a mandatory, nationwide label for food products with GMOs."

"It certainly is not perfect, but it is the best bill possible under these difficult circumstances we find ourselves in today," Roberts added.

Critics, including Sen. Bernie Sanders (I-VT), said the bill's loopholes and allowance for smartphone scanning rather than printed disclosure would limit its effectiveness and create confusion. "When parents go to the store and purchase food, they have the right to know what is in the food their kids are going to be eating," Sanders said on the Senate floor.

What's in the Law

The law defines bioengineered food as that containing "genetic material that has been modified through in-vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature." Food derived from an animal is not considered to be bioengineered solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance (such as GMO corn or soybeans). Meat,

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poultry, or eggs would need to be labeled only if "the most prominent ingredient" would independently be subject to the labeling requirement.

Simply because a food label does not disclose GMOs does not mean that it can also claim to be "not bioengineered" or "non-GMO," the statute says. However, certification of a food under USDA's National Organic Program is sufficient to make such a claim because "organic" food is not allowed to contain GMOs.

USDA must establish a national mandatory bioengineered food disclosure standard within two years and identify the quantity of bioengineered substances necessary to trigger labeling. Small food manufacturers will have one extra year to comply with the rules after USDA sets them and very small food manufacturers, restaurants, and "similar retail food establishments" are exempt.

Critics contend the law's narrow wording will allow companies to not disclose GMOs produced by new technologies, such as "gene editing," and hide the use of highly processed sweeteners and vegetable oils that are made from GMO crops but carry no detectable genetic material. However, USDA contends the legislation gives the agency sufficient authority to consider these matters.

"The bill provides the authority for highly refined sugars and oils to be brought into the program ... as well as the whole host of products derived with traditional gene modification (having gone through the USDA de-regulation process, like corn, soybeans, sugar, and canola) and those derived with gene editing and RNA interference," USDA explained in a statement.

At the center of the controversy is the provision of the law that gives food manufacturers several options for label disclosure, including use of "text, symbol, or electronic or digital link," such as QR or Quick Response Codes that can be scanned by smartphones, or in the case of small manufacturers, a telephone number, so long as the latter two methods carry the words, "Scan here [or call] for more food information." Small manufacturers could also simply publish a website address on the label.

"The bill allows corporations to hide information about GMOs behind confusing QR barcodes that more than a third of Americans can't even read because they don't have smartphones or reliable Internet service," complains Ronnie Cummins, international director of the Organic Consumers Association, which says it gathered 500,000 online signatures opposing the law within a week after Obama signed it.

"The primary objection to the bill is that consumers shouldn't have to scan packaged foods to determine if the products contain genetically engineered ingredients," says Creighton R. Magid, a partner at the Dorsey & Whitney law firm and head of its Washington, D.C. office. The legislation "doesn't make advocates of labeling genetically engineered foods particularly happy, but is a relief to food producers fearful of a patchwork of state labeling laws," he says.

Turf War Brewing?

The law designates USDA, not FDA, as being responsible for overseeing GMO labeling requirements.

"The bill would give USDA these authorities over food labeling that is otherwise under FDA's sole regulatory jurisdiction," the FDA wrote in a June 27, 2016 "technical assistance" document for lawmakers. Because FDA has long held that genetically engineered (GE) foods as a class are safe, the agency "has not expressed a desire to be the responsible agency" for any new program to regulate food labels for bioengineered food, it added.

Nevertheless, "we note that provisions to allow information regarding the GE content of food to be presented only in an electronically accessible form and not on the package label would be in tension with FDA's statute and regulations, which require disclosures on food labels," the FDA added.

Furthermore, "we are concerned that USDA's regulations implementing the mandatory standard under this bill could conflict with FDA's labeling requirements." For example, if a manufacturer couldn't fit both FDA's and USDA's required information on the label. FDA made several suggestions for amending the bill, none of which were adopted.

Organic Food Industry Split

The new law has also driven a bitter wedge in the organic food community, which has established a foothold in the traditional food industry only after years of effort. The Organic Trade Association (OTA), the largest industry group whose membership includes large companies, some of which have been acquired by conventional food conglomerates, supported the federal legislation. Smaller groups, such as the Organic Consumers Association, a nonprofit whose members include small companies and co-ops, opposed it.

"On the surface, we understand how some may be fundamentally dissatisfied with supporting this compromise solution because it includes an option to reveal the presence of GMOs through technology that would require a smartphone and Internet access. But it also covers more products than the Vermont Law," OTA said in a statement. "When it comes to protecting organic agriculture and trade, we have to take the long view. If you consider what the opponents of GMO labeling proposed, and what the voluntary and state by state options would have offered, it's hard not to see how this mandatory federal legislation is a constructive solution to a complex issue."

Consumers Union, which had opposed the federal law, is urging those food companies that are currently labeling their GM products to continue doing so while the new rules are being developed.

"Campbell's, Pepsi, Mars, Dannon, General Mills, Kellogg's, Nestle, and Post Foods are among companies that have already done the work of determining which products have GMO ingredients, and have incurred the expense of changing product packaging to include the required words," says Jean Halloran, director of Food Policy Initiatives at Consumers Union. "We urge companies not to hide this information while waiting for USDA to create new rules."

The new GMO label law "is probably about the best outcome one could have hoped for," says David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. "While this bill may not have given consumer organizations all they want, it is a practical mid-line solution that hopefully will put this issue to bed permanently and allow food companies to focus on real public health issues." ■

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

FSMA Update

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FDA Tackles Terrorism and Adulteration

What you need to know about latest rule and how to respond if a crisis occurs

BY **EDEN GILLOTT BOWE** AND **MATTHEW I. KAPLAN**

The U.S. FDA recently issued its final rule implementing the landmark Food Safety Modernization Act of 2011, a law making the most comprehensive revision to the U.S. food safety system in 70 years. The new rule focuses on insuring food security and preventing intentional adulteration, rather than responding to contamination, illness, or a crisis after the fact. Although the timing was coincidental, the terrorist attack in Nice, France during the summer shows how the failure to focus on seemingly mundane activities like the movement of a delivery van can have tragic consequences, and why this food security rule is essential.

In the rule published May 27, 2016 entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration," FDA states that the purpose of the "rule is to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm." It builds on existing requirements for all registered foreign and domestic food production facilities, applying food security protocols in a regulatory climate that is increasingly concerned about safety.

The approach is modeled on the preventive controls approach used for food safety. It includes the familiar Hazard Analysis and Critical Control Point (HACCP) approach used for seafood and juice processors, and the general hazard analysis and risk-based preventive controls approach underlying the rules governing Good Manufacturing Practices for food facilities. As FDA explains, food safety and food defense "are more similar than they are different." Thus, the framework of the new rule requires an analysis be performed similar to the HACCP approach. This includes identification of significant vulnerabilities, development and implementation of mitigation strategies, and implementation of systematic management components to insure that measures are functioning.

The rule is flexible and rejects a "one-size-fits-all" approach. All facilities are required to conduct a vulnerability assessment and identify actionable mitigation strategies, while acknowledging "the mitigation strategies that [each] facility would establish and implement would depend on the facility, the food, and the outcome of the facility's vulnerability assessment." Because preventive control measures are process-oriented and can be scientifically validated, they are appropriately imposed more broadly. By contrast, security measures typically reduce physical access to prevent intentional contamination by an attacker, but cannot be scientifically validated.

What's in the Rule?

The new rule requires development and implementation of "a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification." The Food Defense Plan sets forth steps each facility will follow to address risks and implement mitigation strategies, but the plan itself is obviously insufficient to avoid intentional adulteration. Thus, it requires implementation of the plan, and development and maintenance of records to document implementation, insuring qualified individuals are performing assigned functions and regular reassessments at least every three years or as needed (such as when there is a process change).

Actionable process steps. Key to any Food Defense Plan is identification of "actionable process steps" for "significant vulnerabilities" at the facility "for each type of food manufactured, processed, packed, or held." It must evaluate potential public health impacts, the degree of physical access, and ability of an attacker (including an insider) to contaminate a product. FDA identifies four key activity types that indicate a significant

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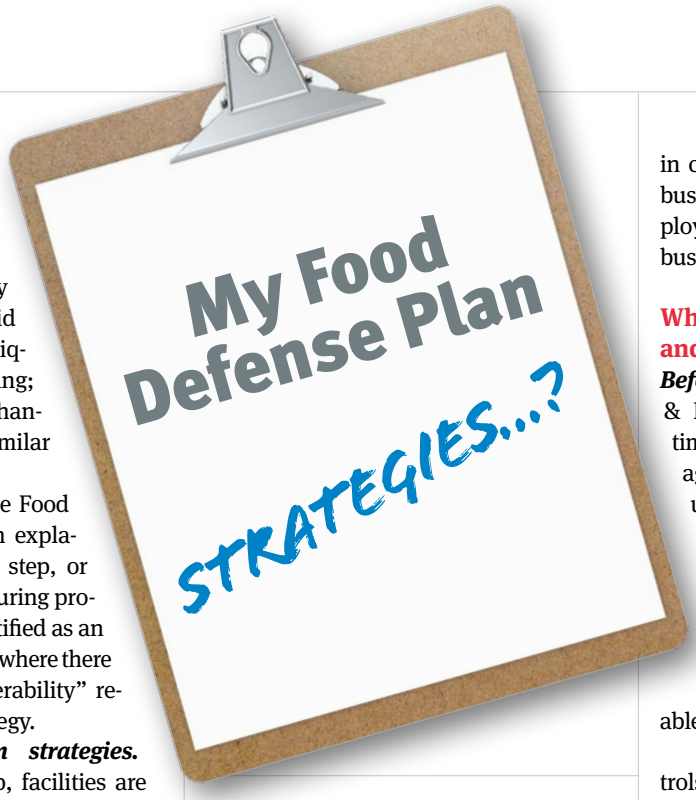

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vulnerability, although others may be identified in individual facility assessments. Those key activities are: bulk liquid receiving and loading; liquid storage and handling; secondary ingredient handling; and mixing and similar activities.

FDA also requires the Food Defense Plan include an explanation why each point, step, or procedure in a manufacturing process was or was not identified as an "actionable process step" where there was a "significant vulnerability" requiring a mitigation strategy.

Focused mitigation strategies. For each actionable step, facilities are required to identify and implement strategies to insure the vulnerability will be significantly minimized or prevented and the food will not be adulterated. The Food Defense Plan must not only identify these strategies, but also explain how they sufficiently minimize or prevent the vulnerability and will be monitored. In the event of a breakdown, corrective procedures must be identified in the Food Defense Plan.

FDA also requires companies to verify and document what has been done and verify that corrective actions are made by qualified individuals. The agency specifically requires a regular review of the monitoring and corrective action records to insure that they are complete, the activities reflected in the records occurred in accordance with the Food Defense Plan, that mitigation strategies are being properly implemented, and that appropriate decisions were made. FDA also requires that the Food Defense Plan include a description of these verification activities, and that records be created documenting the verification procedures.

Are There Exemptions?

Yes, based on size of the business and type of food being processed. Larger businesses covered by the rule may develop a Food Defense Plan that covers only a portion of a facility or certain product lines. Those that average less than $10 million annually qualify as "very small businesses" and are generally exempt.

> The new rule requires development and implementation of "a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification."

The rule does not apply to farms covered by FDA's Produce Safety Rule. It also does not apply to 1) the packing, re-packing, labeling, or re-labeling of food where the existing container of the food remains intact; 2) the holding of food (except the holding of food in liquid storage tanks); 3) most alcoholic beverage manufacturing; 4) on-farm manufacturing, processing, packing, or holding of eggs or game meats by small or very small businesses that conduct only those activities; or 5) animal foods.

When Are the Deadlines?

The Food Defense Rule is currently in effect, however, FDA is deferring enforcement in order to give businesses time to adjust to the rule and implement the necessary changes. Large businesses must be in compliance within three years, small businesses (those with less than 500 employees) have four years, and very small businesses have five years.

What About Public Relations and Legal Liability?

Before a crisis. There is a truism in Crisis & Reputation Management: "The best time to do damage control is before damage happens." By addressing matters up front, you limit or eliminate any legal liability. Do not do the bare minimum. When safety and security are at stake, err on the side of caution. Your actions will demonstrate that the public's well-being is your top priority, and this earns you invaluable goodwill.

It is best to be proactive. Putting controls in place in advance is a relatively modest expense with a high return on investment. They are invaluable to limit liability, or avoid it altogether.

Too often, people and companies think bad things will not happen to them, make half-hearted attempts to be prepared, or procrastinate until the proverbial eleventh hour. These companies end up on the wrong side of the media and the law, playing defense while scrambling to clean up a mess they were not ready for.

With the Food Defense Rule, your legal risks are greatest if someone gets hurt and you've failed to take appropriate action. FDA discussed just such a case—a 2013 incident in Japan involving an employee who poisoned seafood, resulting in at least 2,843 people getting sick and the recall of 6.4 million packages of frozen seafood.

In addition to possible fines, criminal penalties, and the FDA's ability to suspend your food registration and put you out of business, you could face class action or individual lawsuits where the plaintiffs' lawyers will argue that you intentionally failed to follow the law to save money in support of higher damage awards.

During a crisis. Unsure whether or not to disclose a problem or an investigation? Talk to your lawyer, then your public relations team. For public companies, the Security and Exchange Commission requires you to "disclose major events that shareholders should know about."

Whether the event in question rises to that level depends on the severity and size of the public company. For private companies, there are no clear rules beyond a requirement to disclose an imminent and substantial endangerment to the public.

From a brand and reputation perspective, it is best to disclose early and often. Consumers need and want to be reassured. When there is a threat to food safety, they care about one thing: How does it affect them. Failure to inform the public could lead to lawsuits being filed by plaintiffs' lawyers looking to make a buck before the facts are known. Once a suit is filed, you have been damaged regardless of the merit of the allegations. As the bad publicity increases, the risk of additional lawsuits rises and you have to pay your own lawyers to defend the claims.

What do you need to tell the public? Before you say anything, you first must know what you want to achieve. Then you can reverse-engineer your strategy and figure out how to get there.

The basics: How did it happen? What are you doing to fix it? What does this mean for them? Each audience has different concerns—consumers, vendors, investors, and the media. But your messaging must be consistent. If there has been illness or loss of life, show empathy. If you are unsure of an answer, the best thing you can say is, "Let me check on that, and I'll get back to you." That gives you time to craft a well-thought-out response and make sure you have your facts straight. As a rule of thumb, you only need to share the most necessary information. Anything extra (or unplanned or inaccurate) leaves you vulnerable to follow-up questions that you may not want (or be prepared) to answer. This may increase your legal risk.

After the immediate crisis. The hardest part is behind you. The immediate threat is over, and you have figured out what happened. Now, how do you move forward?

You control the story, by either stopping the story or making sure that the audiences who are most important to you quickly hear what happened, what you have done to correct the problem, and the steps you are taking to make sure it never happens again.

Make sure you learn from what happened. Even if years go by without another mistake being made, people will remember what happened and wonder whether you really learned. They will view you more harshly if you did not learn anything. Indeed, the law allows subsequent violations to be treated by FDA more severely. ■

Gillott Bowe is a crisis public relations fixer and president of Gillott Communications LLC. She resolves issues both in and outside the media's glare. She has been featured in *The Wall Street Journal*, *The Washington Post*, NPR, *Forbes*, and *Eater*. Reach her at eden@gillottcommunications.com. **Kaplan** is a partner with Tucker Ellis LLP and co-chair of the firm's Food, Cosmetics, and Nutritional Supplements practice. He advises business on FDA and FTC advertising and labeling compliance and environmental regulatory matters, and defends class action false advertising and unfair competition cases. Reach him at matthew.kaplan@tuckerellis.com.

Industry Insights

How to Combine Your HACCP and HARPC Plans

A combined approach that takes into account the requirements for both standards can help food facilities meet industry expectations

BY **KASSY MARSH**

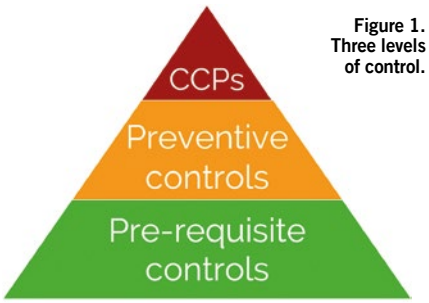

Figure 1. Three levels of control.

The main compliance date of September 2017 for the Preventive Controls Rule for Human Food is fast approaching. Facilities now have the daunting task of trying to amend their current food safety systems to meet the new requirements, which are becoming well known as HARPC (Hazard Analysis and Risk-Based Preventive Controls).

Need for a Combined System

Many facilities already have well-established Hazard Analysis and Critical Control Point (HACCP) or National Advisory Committee on Microbiological Criteria for Foods (NACMCF) based food safety systems. These sites will continue to be asked to comply with HACCP or NACMCF requirements by their customers, accreditation standards, and also by local legislation in the countries to which they export product.

At first glance, the requirements in HACCP or NACMCF and HARPC may look aligned, but facilities must be careful as there are a number of fundamental differences, which need to be considered before making any alterations to their current food safety systems.

The Differences

New HARPC requirements demand a new mindset, which many HACCP specialists are finding difficult to embody.

Although the Preventive Control Rule is very clear about what the food safety plan should achieve, it does not stipulate how it should be laid out and documented. Many of the understood practices from HACCP and NACMCF are not detailed in the rule (such as a scope, product description, intended use, intended user, or a process flow diagram). It could, thereby, be presumed that these elements are no longer required.

However, it would be naïve to think that these key elements could be excluded from any effective food safety plan. Gathering information about the product and process is essential to ensuring that the pertinent hazards are defined. If used properly, these tools can be advantageous to the HARPC system. Plus, facilities need to adhere to the current requirements for food safety, for they will be bound to continue to include this type of information in their system if they want to continue to meet customers' expectations and accreditation.

The Main Discrepancy

There is one fundamental difference between the HACCP and HARPC requirements that requires special attention.

Both systems require hazard analysis to assess the significance of the food safety hazards. Typically, in a HACCP system, the significant hazards would then be assessed to determine which need controlling through the application of a CCP. Contrarily, the FDA indicates that to meet the Preventive Control Rule, all food safety hazards must be assessed *without* taking any current controls into account.

Though this change seems slight, its consequences could be huge, requiring a different approach to ensure the manageability of the system.

With HACCP, the norm is to include all possible hazards, even those unlikely to occur, to make sure all eventualities are covered. During the risk assessment process, these hazards would then be knocked out by accounting for the controls in place.

By applying HARPC principles and assessing this number of hazards without taking the controls into account, the result would be that a high proportion of the hazards would become significant, and therefore, would require the application of a preventive control. The food industry would find itself in a similar situation to when HACCP was first introduced and many facilities, due to the lack of pre-requisites or Good Manufacturing Practices (GMPs), had numerous CCPs. This caused the system to be unwieldy and consequentially ineffective.

Importance of Scoping

The solution is to ensure that only pertinent hazards are channeled into the hazard analysis. To do this in a structured way, so that it can be explained at an inspection with confidence, a methodology is required.

As mentioned above, product description, intended use, intended user, and process flow diagrams can be used to your

KASSY MARSH

advantage at this stage. By detailing such information during the scoping section of the assessment, prior to the hazard analysis, the pertinent hazards that would affect the safety of the product from the inherent characteristics, components, storage conditions, shelf life, food safety treatments, and hurdles, can be extracted.

This method can be used to assess each process step individually and detail the pertinent hazards at that step.

For example, from where a product is chilled, the hazard of *Listeria monocytogenes* during preparation, packing, and storage may be extracted. Or, from where a product is packed with a modified atmosphere, the hazard of incorrect gas content at packing or the use of porous film at the development stage may be extracted. In addition, from where knives are being used to fillet meat or fish, the hazard of contamination from the knife tip during butchery may be extracted.

Hierarchy of Controls

Once the pertinent hazards have been extracted and risk assessed, without taking the current controls into account, a number of significant hazards will have been produced. Each significant hazard will require a preventive control. Those that have been deemed not too significant should be managed through pre-requisite programs (PRPs) or GMPs.

But where do CCPs fit in when a combined HACCP and HARPC system is required? To understand when to apply a CCP, the hierarchy of the controls needs to be understood.

Currently, there are three levels of control that are ordered as seen in Figure 1 on p. 16.

A PRP is a facility wide generic control, one which is applied to more than one step in the process. A preventive control (PC) manages a significant food safety hazard, as defined through the risk assessment.

It is essential to understand the difference between a PC and a CCP. Answering this question was one of the key aspects in the research and development of my book, Combine Your HACCP & HARCP Plan Step-by-Step. The following excerpts from the book are summaries of definitions.

- The FDA define a PC as: "risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."
- The agency also defines a CCP as: "a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level."

Extracting pertinent information from each summary, definitions of PC and a CCP can be devised:

PC: Procedures, practices, and processes to significantly minimize or prevent the hazard; and

CCP: Procedures, practices, and processes at which control can be applied and is essential to eliminate a food safety hazard or reduce such hazard to an acceptable level.

In summation, a PC recognizes when contamination has occurred and either corrects the error or stops the product from being released. A CCP is a control applied to a known contamination issue (such as cooking), which reduces that known contamination to a safe level.

Applying this theory to all the significant hazards generated from the risk assessment can help establish whether a PC or a CCP should be applied.

The Future of HACCP and HARPC

The principles of HACCP were originally published in the 1950s. Despite subtle changes and improvements along the way, its fundamental elements have stayed the same. This type of system has improved food safety over time, but today food safety recalls and withdrawals tend to be related to ineffective PRPs or GMPs.

HARPC is likely to turn HACCP on its head. However, the effects of this change can only be positive. The introduction of PCs as an additional tier of control will no doubt be an advantage. Perhaps in the future, requirements will be combined to produce one robust methodology for food safety risk assessment and control that can be used worldwide. ■

Marsh is the author of the recently released *Combine Your HACCP & HARPC Plan Step-by-Step*. She also co-authored *Assessing Threat Vulnerability for Food Defence* and co-authored *Assessing Error Vulnerability for Food Integrity*. Since starting her own consultancy business in 2012, she has become well regarded in the field of food safety risk assessment. Reach her at kassy.marsh@techni-k.co.uk.

Across The Nation

Wonderful Washington

This Pacific Northwest state is the apple of food safety's eye

BY **LINDA L. LEAKE, MS**

It might be said that Washington takes the popular adage "an apple a day keeps the doctor away" more seriously than any other state. That's because Washington produces more apples than any other state, supplying a whopping 60 percent of the domestic market and 90 percent of all apples exported from the U.S., boasts the Washington Apple Commission.

The only state named after a U.S. president also takes food safety seriously.

At the core of the outstanding food safety efforts in the place that, along with California, Alaska, and Hawaii, is one of just four states that have active volcanoes, is the Washington State Department of Agriculture's (WSDA) Food Safety and Consumer Services Division (FSCSD). With all the power of Mount St. Helens, great food safety initiatives flow freely from the FSCSD.

The Division's Food Safety Program (FSP) is responsible for compliance, including the licensing, inspection, and sampling of food processing facilities, food warehouses, and dairy farm operations throughout the state, says Susie Bautista, recall coordinator for the WSDA Animal Feed and Rapid Response Program (Feed/RRP).

"The FSP also helps food firms by providing technical assistance on food safety issues," she elaborates. "The FSP works closely with the dairy industry to maintain the ability to ship milk and milk products out of state, as well as with FDA and the Washington State Department of Health (WSDOH) in conducting investigations when pathogens are found in foods or consumers become ill from eating food products."

After apples, milk is the Evergreen State's second leading agricultural food and feed commodity, followed by wheat, potatoes, cattle/calves, hay, sweet cherries, grapes, pears, and hops.

Washington is also a major producer of stone fruits, fish, shellfish, carrots, onions, and mint oils.

"The FSP continues to expand into new food production scenarios, such as cottage foods, low risk products made in home kitchens, and also marijuana infused edibles, for which the state Liquor Control Board contracts the FSP to conduct sanitation inspections," says Michael Tokos, FSP assistant manager.

According to Bautista, some recent federal funding cooperative agreements the FSCSD has received include a Food and Feed Emergency Rapid Response Team (RRT), a Food Protection Task Force (FPTF), a recall coordinator with Food Safety Modernization Act (FSMA) readiness, a human food sample coordinator with FSMA readiness, a Food Emergency Response Network, Manufactured Foods Regulatory Program Standards (MFRPS), and Animal Feed Regulatory Program Standards (AFRPS).

There are approximately 2,200 food and feed manufacturing facilities in Washington State that are, or will eventually be, regulated under the new FSMA rules.

"Washington was just the second state in the nation to successfully meet all the MFRP standards," interjects Candace Jacobs, DVM, assistant director of the FSCSD. "Washington is entering its second year with the AFRP cooperative agreement and continues to make great progress on implementing its 11 standards."

Rapid Response Team

With FDA support, the WSDA established its RRT in 2009. "Since then, we've been able to foster lasting relationships between several food and feed safety related partners, including FDA, the WSDOH, Food Safety and Communicable Disease Epidemiology Programs, USDA APHIS and FSIS, local health jurisdictions, and academic institutions throughout the state," says Randy Treadwell, MPH, RRT program manager.

"Through assistance from the Washington RRT, the WSDA Microbiology Laboratory has been able to add high performance liquid chromatography and whole genome sequencing to their list of capabilities," he relates.

Treadwell says the Feed/RRP has recently revised a routine feed sampling plan, which augments the sampling conducted under FDA contract in order to create a more complete profile of animal food types, distribution, and safety within Washington State. "Any positive pathogen results in feed are coordinated through the Washington RRT, which keeps all partner programs and agencies informed on response activities and next steps," he says.

"Having the Feed/RRP provides a close cooperation between staff who inspect food and feed establishments, as there are many areas where they are intertwined and interrelated," adds Ali Kashani, PhD, Feed/RRP's senior feed advisor. "Not always is food safety achieved if a major component, which is feeding animals for production of human food, including meat, eggs, and dairy, is not completely considered."

The Feed/RRP has helped FARM stay abreast of recall notices and activities that greatly affect the state's emergency food system, says Kim Eads, manager of the WSDA food assistance programs. "FARM works with approximately 500 food pantries and meal programs in every part of Washington State, to serve one in six Washingtonians in need of food," she relates.

"Through the FPTF and the RRT, Washington's regulatory agencies are better prepared to quickly respond to food and feed emergencies and related public health events, says Phil Wyman, a health and environmental investigator with Public Health—Seattle & King County.

King is Washington's most populous county (about 2.1 million people).

According to Wyman, the creation of the RRT was one of the inspirations that lead King County to develop its own Foodborne Illness Investigation Team (FIIT). "Implementing the FIIT has resulted in more thorough and timely outbreak investigations," Wyman relates.

"Further, the FIIT has been better able to identify and institute targeted interventions, stopping outbreaks right in their tracks."

"Washington is a leader in food safety training and we provide exceptional training for retail food inspectors," says Joe Graham, the food safety program supervisor for the WSDOH. "This includes regular annual safety workshops across the state and regular three-day New Inspector Training for beginning food inspectors."

A key NWFPA and WSU collaboration is the annual two-day Northwest Food Safety & Sanitation Workshop, which NWFPA sponsors each November.

Epidemiologists

Newly added polymerase chain reaction-based clinical diagnosis is both enhancing and complicating public health efforts in Washington, says Jeffrey Duchin, MD, health officer and chief of the Communicable Disease Epidemiology and Immunization Section of Public Health—Seattle & King County.

"As a result, there are more reports of foodborne illness than before this technology was implemented," he says. "But, due to budget constraints, there's been no increase in our team members, so we are all busier working harder than ever before. In addition, non-culture-based diagnostic testing means we don't have organisms of epidemiological value to study during outbreaks."

Epidemiologists handled some 15 foodborne illness outbreaks in King County in 2015.

"King County has taken recent steps to improve the foodborne disease disclosure process," Dr. Duchin reports. "The public and the media can click on 'communicable diseases' on our website and access information rapidly."

Processors

A real boost to the Northwest Food Processors Association (NWFPA) consumer-

(Continued on p. 20)

(Continued from p. 19)
focused food safety efforts since 2013 has been the organization's offering of free membership to small companies with less than $1 million in annual revenue, says David McGiverin, NWFPA president.

"Our board saw the value of welcoming small microprocessors to have access to all of the educational and training programs we offer," he relates. "Since maintaining food safety is not easy and retailers' buying policies can vary relative to new products, we believe our programs benefit small processors by lowering any barriers to food safety expertise they may have."

The NWFPA's current membership totals some 160 processor companies, including more than 40 based in Washington, McGiverin notes. NWFPA also boasts more than 350 supplier members.

Another strength of the NWFPA is its Operations and Technical Affairs Committee that reviews the latest food safety trends in the early stages. "Using that data, we then collaborate with our partners like WSDA and Washington State University (WSU) to ensure our members have the latest and most relevant information and training to meet their food safety needs," says Brian Campbell, NWFPA's director of food safety and policy.

Training

A key NWFPA and WSU collaboration is the annual two-day Northwest Food Safety & Sanitation Workshop, which NWFPA sponsors each November.

Campbell calls this event "the best regional sanitation workshop of its kind in North America."

Other co-sponsors of the workshop are the Oregon State University Extension Service and University of Idaho Extension. The workshop is held in cooperation with WSDA, the Oregon Dept. of Agriculture, the Seafood Products Association, and the Western Association of Food and Drug Officials.

"The workshop benefits 'boots on the ground' people, and addresses basic sanitation, as well as cutting edge issues related to food sanitation and food safety," Campbell explains.

Girish Ganjyal, PhD, an extension food processing specialist at WSU, is an organizer and instructor for workshop.

According to Wyman, the creation of the RRT was one of the inspirations that lead King County to develop its own Foodborne Illness Investigation Team (FIIT).

"In 2016 we are adding a new award to the sanitation workshop agenda, Best Line Worker," Dr. Ganjyal mentions. "Our steering committee strongly believes that this award will be very important to help recognize the contributions that our line workers make to food safety."

Seafood

Washington's fishing and seafood industry generates nearly $15 billion in direct and indirect annual revenues, according to a 2013 Washington State Maritime Cluster Economic Impact Study.

Declining catches, competitive markets, constantly changing practices, and the challenge of finding new employees make smart business practices essential to sustaining Washington's fishing industry, says Pete Granger, MBA, a seafood industry specialist with Washington Sea Grant (WSG).

Based at the University of Washington, WSG provides safety training, technical guidance, and research to Washington's fishing and seafood communities.

Consumers often wonder if the fish they buy is healthy, high-quality, and sustainably caught, Granger notes. To help seafood workers respond to customer inquiries regarding these concerns, under Granger's leadership, WSG designed and launched in 2008 a 12-hour course in seafood retail for apprentice meatcutters, offered in conjunction with the meatcutter apprenticeship programs of South Seattle Community College and the United Food and Commercial Workers International.

"Trainees learn about seafood product origin, sensory evaluation, quality maintenance, safety, sanitation, marketing, and promotion," Granger relates. "Each trainee receives a comprehensive manual with waterproof pages for counter use. Afterward they are evaluated on their retention of seafood information and surveyed about customer knowledge and training impacts."

About 25 students complete the apprenticeship annually, Granger reports.

"Having a better informed person behind the seafood counter means customers get better information about the quality and safety of the seafood they are buying," Granger says about benefits of the program.

As a technical trade organization, the Seattle-based Seafood Products Association (SPA) serves its 50 Pacific Northwest-based member companies in the areas of regulatory compliance and conformance with customer requirements related to food safety, quality, and legality, says Christopher Rezendes, SPA president.

"Our members process all seafood species, including fin fish, crustaceans, and mollusks," Rezendes says.

"The SPA's long-standing Salmon Control Plan has fostered and facilitated a cooperative relationship between the FDA and the seafood industry," Rezendes points out. "It has provided a format for addressing compliance issues, cross-training, and exceptional dialogue with the FDA, as well as other state regulatory agencies. Under this program, all representative lots of canned salmon are examined for quality before distribution to the market place."

Rezendes mentions that SPA's member processors have operated under the FDA's Fish and Fishery Products Hazards and Controls Guidance since 1997, and the canneries have operated under the FDA's Guidance for Commercial Processors of Acidified & Low-Acid Canned Foods since 1972.

"For SPA members, producing safe and wholesome products through science-based programs and cooperative agreements has long been paramount to success," Rezendes emphasizes. "Our members strive for compliance with high standards and exude a cooperative spirit with regulatory authorities." ■

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

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The Emerging Water Crisis

Beverage manufacturers face dual threats of water contamination and shortages in every drop

BY **TED AGRES**

As essential as it is for beverage manufacturing, water has long been taken for granted, both in terms of availability and quality. This is changing, as droughts in California and chronic water shortages in other parts of the world begin to impact food industry profits. U.S. beverage manufacturers are also realizing the potential dangers they face from using municipal water, which may be contaminated with lead, chemicals, and microorganisms, as their primary ingredient and for plant cleaning and cooling. And despite newly enacted EPA and FDA regulations, significant oversight gaps remain when it comes to water use in beverages.

It's not surprising, then, that water issues are becoming more prominent with the domestic and international beverage industries.

"Water quality is among our industry's highest priorities," says William M. Dermody Jr., vice president, policy, American Beverage Association (ABA), the U.S. non-alcoholic beverage trade group. "Every [member] company has robust processes in place to ensure water purity, and the beverage industry supports and depends on a safe and high-quality municipal water infrastructure," he tells *Food Quality & Safety* magazine. ABA's membership includes the "big-three" beverage makers—The Coca-Cola Co., PepsiCo Inc., and the Dr Pepper Snapple Group, which together account for about two-thirds of the U.S. soft drink manufacturing market.

Carbonated soft drinks comprise about 45 percent of the U.S. non-alcoholic beverage industry's revenue, followed by fruit juices and beverages (15 percent); bottled waters (13 percent); functional beverages, such as energy, relaxation drinks, and ready-to-drink teas and coffees (11 percent); sports drinks (8 percent); and ice manufacturing, dairy- and soy-based drinks (7 percent), according to an analysis by ChangeLab Solutions. The ABA estimates the non-alcoholic beverage industry contributes about $169 billion to the U.S. economy annually. Worldwide sales of soft drinks and bottled water

exceed $260 billion annually, according to the market research firm IBISWorld. So much of what is at stake depends on water.

Managing Water Usage

This, of course, is because water is the primary ingredient of beverage products, constituting 90 percent of sugar-sweetened soft drinks and up to 99 percent of diet sodas. But beverage manufacturers, like other food producers, also use water for material washing and moving, cooling and air conditioning, and equipment cleaning and disinfecting. In fact, two-thirds of all non-product water used in food production is for cleaning in place and heat exchange (cooling towers), according to a recent whitepaper from Haskell, an engineering and design firm. The remaining one-third is split between manual cleaning, sanitization, and miscellaneous utility demands. Coca-Cola's bottling facility in Detroit consumes an average of 1.7 gallons of municipal water per gallon of finished product, according to a 2012 University of Michigan study. While that continues to be the average ratio, Coca-Cola says some of its bottling plants have reduced it to 1.4:1.

To enhance in-plant water conservation, Coca-Cola and most large beverage manufacturers treat non-product water for reuse. Spent water can be treated using a variety of techniques, among them membrane filtration, reverse osmosis, UV and ozone disinfection, and nano-filtration, depending on the water's quality and subsequent application. To be used for cleaning, for example, recycled water must be at least of drinking water quality and even higher if intended for boiler makeup. Rather than discharging reclaimed water, facilities can use it for warehouse floor washing or landscaping.

While conservation at the manufacturing level is important, a much larger issue is total water usage, or the "water footprint," which extends back to crop cultivation (typically sugar beets) and sweetener production (wet milling). In a study done jointly with the Nature Conservancy, Coca-Cola estimates it has a 70:1 total water ratio, meaning every 1 liter of finished product requires 30 liters of green water (rain water stored in the ground), 16 liters of blue water (surface and groundwater), and 24 liters of grey or waste water (water spent or used to assimilate the pollution load).

Usage estimates can vary widely. The Water Footprint Network, a nonprofit research group that works with companies and governments on conservation issues, estimates it takes 170 to 310 liters of water to produce a half liter of a typical sugar-sweetened soda (340 to 620:1 ratio). The ingredients needed for one cup of brewed coffee require 140 liters of water, while 1 liter of beer requires 300 liters, from hops field to mug.

The fact is that drinkable water sources are limited: Only 2.5 percent of the world's water supply is freshwater, and two-thirds of that is locked up in glaciers. Much of the accessible freshwater is polluted and quality is deteriorating worldwide. At present usage rates, global demand for water will exceed viable resources by 40 percent by 2030, according to McKinsey & Company. Water scarcity is already impacting beverage and food companies, particularly in drought-stricken areas.

Coca-Cola, for example, scrapped plans in April 2015 to build an $81-million bottling facility in southern India after farmers complained about strains on local groundwater supplies. J.M. Smucker raised prices on Folger's K-Cup coffee packs to offset the effects of Brazil's worst drought in decades. Food producers are likewise impacted: Campbell Soup Co. saw a 28 percent profit decline in its California-based carrot division in early 2015 due, in part, to droughts followed by heavy rains. Unilever, whose brands include Lipton, estimated that natural disasters linked to climate change, including water scarcity, food price increases, and reduced productivity, cost the company about $400 million annually.

But beverage manufacturers, like other food producers, also use water for material washing and moving, cooling and air conditioning, and equipment cleaning and disinfecting.

"Water risks are already affecting corporate income statements and balance sheets" because of operational disruptions and limits on growth, concludes a recent study by Ceres, a nonprofit group that advises institutional investors on environmental issues. Of 31 publicly traded major food companies Ceres studied in 2015, 90 percent cited access to water as a "material risk" in their 10-K financial filings. "Our companies are deeply involved in ensuring the sustainability of clean water sources for all," ABA's Dermody explains. "And our water resource managers work with environmental groups and water authorities nationwide to improve watersheds and aquifers, and will continue to do so."

Navigating the Quality Risks

When it comes to water quality, EPA, state, and local agencies have jurisdiction over municipal drinking water (tap water) while FDA regulates bottled drinking water and manufactured beverages, including flavored water and nutrient-added water beverages. FDA's current Good Manufacturing Practices (cGMP) standards for bottled water include requiring producers to process, bottle, hold, and transport bottled water under sanitary conditions; protect water sources from bacteria, chemicals, and other contaminants; use QC processes to ensure the bacteriological and chemical safety of the water; and sample and test both source and final product for contaminants.

The Food Safety Modernization Act (FSMA) requires beverage manufacturers to ensure the quality of all ingredients, including water. Large beverage manufacturers became subject to FSMA's cGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule in September 2016, says FDA spokesperson Evelyn Pereira. (Juice manufacturers are subject to their own Hazard Analysis and Critical Control Point, or HACCP, regulations and are not bound by FSMA preventive controls requirements.) However, it wasn't until August that FDA issued draft guidance for industry compliance with the FSMA preventive controls rule.

"This is good, but facilities amenable to FSMA preventative control rules were trying to be prepared for enforcement beginning in September," notes Craig Henry, PhD, vice president of business

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FSMA requires beverage manufacturers to ensure the quality of all ingredients, including water.

(Continued from p. 23)

development, Decernis LLC. "Industry still desperately needs commodity-specific guidance for human food, and water is the single most common ingredient in food products around the world," he tells *Food Quality & Safety.*

FDA regulations implicitly assume EPA-compliant municipal water is safe for consumption. But, unfortunately, this is not always the case. EPA's rules for public water systems require that utilities meet treatment standards for 95 percent of the water they distribute. EPA does not dictate how water must be treated, and not all municipal water is disinfected the same way, and some is not disinfected at all. This means that EPA-compliant water could be contaminated with *Salmonella* spp., viruses, or other pathogens. For beverage manufacturers that use between 10,000 and 500,000 gallons of municipal water per day, 5 percent contamination could be significant, not only for the product but also for potential cross-contamination within the plant.

"FSMA makes clear that food and beverage manufacturers need to ensure the biological integrity of water if they use it as an ingredient. But if they use municipal water, it is not clear that they need to do an appropriate risk assessment," says Phyllis Posy, vice president, strategic services and regulatory affairs, Atlantium Technologies, which makes UV-light based water disinfection and treatment equipment for industry and municipalities.

Further complicating matters, EPA's Revised Total Coliform Rule for public water systems, which went into effect April 1, 2016, changes the focus for utilities from public notification of problems to "find and fix" without notification, Posy says. The revised rule focuses on detecting and reducing maximum levels of *E. coli*, a proxy for other contaminants, including viruses, which are not tested. "Reduction in fecal contamination *should* reduce the potential risk from all waterborne pathogens including bacteria, parasitic protozoa, and their associated illnesses," EPA explains. Under this new framework, manufacturers and the public may never know of a contamination problem.

"The intent of FSMA is to ensure safer food, but the letter of the law allows a lot of wiggle room," Posy tells *Food Quality & Safety.*

Municipal water systems, most of which are aging and needing repair, are also prone to other forms of contamination, including lead, as residents and businesses in Flint, Mich. and counties in Alabama have found. Unsafe levels of industrial chemicals, including PFAS (poly- and perfluoroalkyl substances), have been found in 66 public water supplies serving 6 million people. The chemicals, commonly used in manufacturing household products, have been linked to cancers and other serious health problems. In many rural areas where people rely on wells and groundwater, contamination from hydraulic fracturing or "fracking" is a major concern. And when a natural disaster strikes, such as a Hurricane Katrina or Sandy, municipal water frequently requires a boil advisory—something manufacturers are unable to do.

"In case of a natural disaster or contamination, if the beverage manufacturer hasn't done anything in advance, it's too late," says Posy. "The question is not what they should do now when there's a mess, but what should they have done in advance? They should have done a risk assessment to understand where their water's coming from, and not take water for granted."

Nearly all large beverage manufacturers do treat incoming municipal water not only for potential contamination but also because of flavor profile requirements; cola syrup simply doesn't taste right when added to chlorinated water. "But when there's not a flavor profile issue involved, smaller beverage manufacturers may assume that because the municipal water's good enough to drink, it must be good enough to make food and beverages," Posy says. "Unfortunately, that's not always the case."

Beverage manufacturers today have a large and growing array of test and treatment technologies, depending upon their products and manufacturing needs. Similar to equipment used to recycle water waste within the plant, these can include activated carbon filters to remove sediment particles, chlorine, bromine, and organics; reverse osmosis to remove dissolved inorganic solids; micro-, ultra-, and even nano-filtration membrane systems to separate microorganisms and total dissolved solids; ion-exchange resins or polymers to remove heavy metals and maintain color and taste consistency; and UV-light and ozone systems to kill bacteria in water and on surfaces and to sanitize storage tanks, vessels, and piping. Large bottling facilities always test their incoming water to measure chemicals and microbial contaminants, and test finished product for QC and safety.

"If you take your water supply for granted and think it will be okay in the end, it will not be okay," says Posy. "Water problems in a beverage manufacturing facility don't come about from spontaneous generation; they get transmitted from the water supply. And that water could provide the circulatory system for making what may have started as a problem become a catastrophe." ■

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

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India's Water Challenges

Addressing the many variables of water testing and purification

BY **SAURABH ARORA, PHD**

Access to clean drinking water is a human right. However, providing safe water to India's millions is a challenge of no small proportion. According to a report by WaterAid, an international organization working to provide water sanitation and hygiene, more than 80 percent of India's surface water is polluted. Waste and industrial effluents are dumped into rivers, seas, and lakes. Agricultural run-offs that contain pesticides and fertilizers, road run-off, industrial leaks, and untreated sewage flow into water bodies. In addition, rapid depletion of ground water, variability of terrain, and incongruity in the quality of raw water treatment intensify this cocktail of issues that continues to derail water purification and water testing systems in the country.

Testing and water treatment methods vary according to usage. The Bureau of Indian Standards (BIS) specifies water standards in India for various purposes. Drinking water, potable water, and domestic use water quality standards must comply with IS: 10500; water used in the food processing industry must follow standards as per IS: 4251; water for irrigation and recreational purposes (i.e. in swimming pools), the standards must be as per IS: 3328; and packaged drinking water standards need to be IS: 14543 compliant.

The Issues

In spite of these standards, water testing and treatment are neither regularly followed, nor strictly enforced due to hurdles such as a dearth of resources and funds provided by the government. Studies pointing out that Indian people are affected by raw water quality are not to be discredited. In many areas, water contains excessive levels of iron, fluoride, salinity, nitrate, and arsenic. Microbial contamination from unclean water supplies causes thousands of cases of diarrhea, typhoid, and viral hepatitis every year. The Indian government might accept WHO Guidelines for Drinking-Water Quality, but unless standards for drinking water are effectively enforced, public health risks will remain.

Treating drinking water is a demanding process that varies according to the use of water and contaminant vulnerability in the water source. Potable drinking water in India—even with treatment—could still contain toxic and infectious materials. Most potable water supplied by civic authorities has not received proper treatment. In rural areas most households get piped water that is largely untreated and in urban areas people use their own filters to purify water. With this public health risk, India has seen a rise in cases of waterborne diseases like diarrhea, cholera, jaundice, etc.

This same contaminated water is being supplied to the Indian food industry, jeopardizing consumer health through processed foods. The country's food regulatory body, Food Safety and Standards Authority of India (FSSAI), has strict standards for the water being used in the industry. An important regulatory requirement that all food business operators must follow is to get the water they will be using in food preparation and processing tested to ensure compliance with BIS standards and potable water standards of FSSAI. Though water quality is already monitored by municipal boards, their testing analyses are not made public; therefore, FSSAI requires the food industry to carry out additional testing.

Besides surface water, groundwater is the major source of drinking water in India; nearly 85 percent of the population is dependent upon it. However, due to over-exploitation to meet irrigational demands and fulfill excess water requirements in hot weather, ground water is quickly deteriorating. Deep drilling of aquifers to access ground water may be contaminating drinking water sources with natural contaminants like fluoride, arsenic, and saline. The Central Pollution Control Board (CPCB), which monitors water contamination, has reported arsenic contamination in eight states and fluoride contamination in 19 states. High salinity has been reported in 15 coastal and inland states, iron in 19 states, and nitrate in 12 states.

Organic contamination comes from a number of sources in India—primarily, untreated sewage. Sewage in septic tanks and pit latrines have become major contributors to groundwater and surface water pollution. According to a CPCB survey, nearly 66 percent samples of water have bio-chemical oxygen demand values (used for measuring organic pollution) lower than acceptable levels, and 44 percent of the samples contained coliform. BIS standards indicate that no coliform should be present in drinking water. There are also new chemical threats to water quality known as persistent organic pollutants. These are polychlorinated biphenyls, widely used in capacitors, transformers, dioxins, and furans in the cement and pipe industry. They remain in the environment and when consumed (via contaminated water) cling to fat tissues of the body.

Raw water quality varies apropos the variability of pollutants found in water sources. This means that effective water treatment methods require constant modification. In India, carrying out modified treatments is an unfeasible task: Treatment plants lack both material resources and the knowledge required for action. There is a deficit of trained technicians who understand the intricacies in determining the method of treatment that will respond to a pollutant. One example cited by CPCB is that water treatment personnel lack the knowledge that trihalomethanes can form due

to chlorination of organic matter; this is a basic factoid. Also, most water treatment plants do not employ chemists, who can aid facilities in the face of increasing pollution.

Recent research indicates that the percentage of tested water sources varies greatly by state. Sampling protocols are not fully specified and the proportion of negative water test results is very high, running contrary to the number of pollutants reported in studies. Negative sampling results could be attributed in part to the fact that the sampling of sources is limited to groundwater and protected wells. This limited testing doesn't provide a full picture of the level of water quality from all sources. The majority of positive test results involve chemical contamination, whereas, biological contamination reports are sparse, despite massive concerns about sanitation in rural environments and sewage leaks in urban areas. The inability to enforce appropriate safety measures only adds to the woes resulting from rampant contamination and negligence.

Government has launched several programs at the national, state, district, block, and Panchayat levels to monitor water quality, but its effectiveness doesn't manifest. One reason is redundancy: There are too many governmental bodies, ministries, and institutions tackling water issues. Success is contingent upon proper coordination amongst these agencies. With the low level of education prevalent at the village level, building awareness and training Pancahyat bodies requires large scale organization.

Another obstacle is proper and continual monitoring and testing of water so that water sources can be assessed throughout the year. This requires well-equipped laboratories and trained technicians as water testing field kits don't necessarily yield accurate results. Sometimes, even when analytical data presents accurate results, sufficient treatment is not viable or modern water purification technologies are not available.

A Better Future?

The government recognizes that dealing with the issue of water quality is a major challenge. It aims to address the issues of water quality surveillance and monitoring by setting up more testing laboratories with qualified manpower, equipment, and chemicals, which can provide uniform data that is sharable amongst all agencies involved. In doing so, the government must not overlook pre-existing infrastructure—there already exists a large number of food and water testing laboratories that are recognized by the National Accreditation Board for Testing and Calibration Laboratories and the FSSAI. These private laboratories have the latest equipment and technical backup to carry out broader water testing services throughout the country. Invoking private players into water treatment may increase accountability and provide greater access to purified and safe drinking water to Indian citizens. ■

Dr. Arora is founder of FoodSafetyHelpline.com and heads the services divisions of Arbro Pharmaceuticals and Auriga Research in India. Reach him at saurabharora@arbropharma.com.

For complete story, go to www.foodqualityandsafety.com and type in "India's Water Challenges" in search box.

FONA: More Than Just Great Flavors

The 2016 Food Quality & Safety Award-winning company excels at being audit-ready, implementing the latest technology, and investing in its employees

BY **LINDA L. LEAKE, MS**

When Joseph Slawek was a student at St. Patrick High School on Chicago's Northwest side, he'd hop the city bus in his Portage Park neighborhood and travel three and a half miles to a job at Food Materials Corporation, a flavors manufacturer located at California Avenue and Irving Park Road.

During the school year, starting when he was 16, he'd work four-hour shifts evenings and Saturdays, clocking about 20 hours a week. Come summer, he was a full-timer during the week, and he also seized opportunities to work overtime shifts on Saturdays whenever possible. Slawek's entry level duties varied from sweeping floors to helping extract vanilla from vanilla beans.

"Food Materials Corporation was a flavor company with a particular strength in vanilla," Slawek relates, noting that the Windy City company was eventually purchased by the New York-based International Flavors and Fragrances, Inc.

During those early days in the plant, Slawek never dreamed he would not only work at Food Materials Corp., as it was familiarly called, for 21 years, but that he would one day establish his own exemplary, globally respected, award-winning flavors company.

In 1987, Slawek enthusiastically pursued his dream of developing what he calls "a new kind of flavor company." He envisioned building an organization that could compete with the largest international flavor companies across a range of market segments, but also connect with customers by developing close relationships in a congenial, small company fashion.

I want to thank the magazine for the prestigious Food Quality & Safety Award. It's a great honor for us.

—Slawek

Joseph Slawek, board chairman and CEO, FONA.

Meet Slawek's brainchild, FONA International, winner of the 2016 Food Quality & Safety Award. This prestigious honor from *Food Quality & Safety* magazine recognizes the dedication and achievement of an organization that upholds the highest food standards supported by quantifiable results.

"Our founding vision was to be the high-tech, high-touch alternative to business as usual in the flavor industry," Slawek says. "Our approach to serving the needs of food and beverage manufacturers has always been to combine world-class expertise, technology innovation, and quality programs. To that we apply entrepreneurial energy and values-driven culture to deliver unmatched service, speed, quality, and flexibility."

Under Slawek's leadership, first as a salesman, president, and CEO, and now as board chairman and CEO, FONA International creates and produces flavors (some 2,329 different, unique flavors in 12 months leading up to August 2016) for many of the largest food, beverage, and nutritional companies in the world. FONA offers flavor solutions for the confection, grain, beverage, performance nutrition, over the counter, and emerging markets from its state-of-the-art 33-acre headquarters campus in historic Geneva, Ill.

The truly global FONA also has locations in Canada (for sales, flavor creation, prototyping/applications, redundant lab, manufacturing, and distribution), China (which includes a customer innovation center, customer training center, sales, flavor creation, prototyping/applications, sensory testing, distribution through all of APAC, and manufacturing), the U.K. (which features sensory testing, manufacturing, and distribution), and Mexico (home of logistics and distribution for all of Latin America). FONA also has strategic partnerships in India and Australia.

Top Priority: Food Safety

"By the time I founded FONA, I knew that food safety was the top priority for us as an organization," Slawek says. "By that time in my career, I knew that our very existence required that we commit our resources to safe, high-quality, audited facilities, and which, by extension, means safe products. At FONA, we have been, and will always be, dedicated to food safety as an essential principle."

This dedication is spelled out in FONA's mission statement:

We strive for excellence in all endeavors. We set our goals to achieve total customer satisfaction by delivering premium quality

FONA INTERNATIONAL

specification-conforming products and exceptional service, second to none. On this we will not compromise.

So what are FONA's secrets to food quality and safety success?

Audit-Ready Lifestyle

"We have some principles within FONA that we try to live by," Slawek begins. "We work hard to be audit-ready 24/7. We want to live an audit-ready lifestyle that allows our customers and industry organizations like AIB (American Institute of Baking) and SQF (Safe Quality Food) to inspect us with or without notice. At FONA, we welcome them with open arms. We want them to see that we strive to be audit-ready 24/7."

FONA has been a leader in SQF, Slawek emphasizes. "FONA first achieved SQF certification in 2009 and was SQF Manufacturer of the Year in 2012," he mentions. "At FONA, we view customer audits as an opportunity to improve, as an external organization reviews our processes and offers advice and consultation. As a result, employees are reminded each day of FONA's commitment to food quality and safety."

That commitment includes all-important monetary investments. Slawek points out that, every year, FONA invests six-figure amounts in state-of-the-art analytical equipment alone, with more than half a million dollars invested during 2015 and 2016.

"In the past year, instrumentation upgrades for FONA's product safety and quality laboratory include two automated instruments to perform refractive index and specific gravity," says John Budin, PhD, FONA's director of product safety and quality (PS&Q). "A second Fourier transform infrared spectrometer was added to evaluate some raw materials for purity."

A Setaflash flash point unit was acquired to compliment other flash point methods FONA uses.

"All flavors must have a flash point to satisfy U.S. Department of Transportation requirements for proper packaging and shipping," Dr. Budin points out.

For research and innovation, FONA purchased a high-end Gerstel autosampler for gas chromatography. "This autosampler is connected to an Agilent gas chromatograph, coupled with a triple quadrupole mass spectrometer," Dr. Budin relates. "This instrument has also been useful for troubleshooting non-conformances."

John Budin, product safety and quality director, FONA.

In 2015 FONA installed an electronic temperature monitoring system for the company's walk-in cooler, which is used to store some raw materials and a few finished goods. "This system notifies team members immediately via their work cellphone if the cooler reaches a pre-determined temperature," says Dr. Budin. "The benefit is they can respond quickly with corrective action."

Also in 2015, FONA upgraded its campus-wide camera systems to enhance the food defense program with higher resolution of recordings.

FONA's newest big thing is a laboratory information management system (LIMS). It was purchased and configuration began in May this year, following a successful proof of concept phase (POC) launched in December 2015.

"The intent of the POC was to map business software and instrumentation to assure that LIMS was compatible with FONA's existing systems, and also to assure that the project was accurately budgeted," says Janis Diasio, FONA's PS&Q project manager.

The company expects to see a great number of LIMS benefits, such as improved laboratory and quality monitoring efficiency, and greater business intelligence, traceability, and transparency, Diasio relates.

Jonathon DiMaggio, FONA's analytical laboratory supervisor, emphasizes that what makes this amount of investment even more impressive is the relative size of FONA and its ability to sustain growth. The company continues to grow and increase in revenue year after year, which is unusual in the food industry, he notes.

"FONA is a mid-sized, privately-owned flavor company," DiMaggio points out. "So the investment in high-tech and high-quality systems and instrumentation is truly remarkable. It shows the company's commitment to quality. Plus, it enables us to compete with the largest flavor companies in the world, and win."

The investment and initiatives implemented at FONA have made large, positive impacts on the business, DiMaggio adds. "The impact of reducing test turnaround time has made FONA more competitive in the flavor industry," he elaborates. "The impact of reduced customer non-conformances and improvement of percent on time to commit are dramatic."

As testament to the company's commitment to food quality and safety, FONA has established this list of core values that are instilled in each employee:

1. Do the right thing for all stakeholders in all situations;
2. Demonstrate a relentless, passionate partner-centricity;
3. Establish and nurture a high-performance work environment;
4. Effectively steward our resources and opportunities;
5. Invest consistently and effectively in our growth and innovation;
6. Share generously with our people and community; and
7. Outperform our industry in pursuit of profitable growth.

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"One health and safety principle that we live by, and something we always say, is that we want to send our people home safer and healthier than when they came to work," Slawek adds. "That's why we have employee benefits like health programs, CPR (cardiopulmonary resuscitation) training, safety training, and fitness classes, to name a few."

FONA management is extremely proud of the feedback received from MRA (The Management Association), an independent third party who conducts their biannual, company-wide employee engagement studies. This study is a 72-item questionnaire that measures employee engagement and satisfaction, and is rated as favorable or unfavorable for each question.

In the 2015 study, FONA's PS&Q team had 82 percent of their staff stating that they are engaged in their job, compared to a national manufacturing industry norm of 30 percent. The employee engagement of the PS&Q group improved by 49 points from 2013, the largest gain among FONA's other departments. The PS&Q group as a whole reported a 97 percent satisfaction with their jobs, compared to 80 percent as a national norm for a non-union manufacturing setting, as compiled by MRA.

Menzie Clarke, senior flavorist, FONA, teaching at Flavor University.

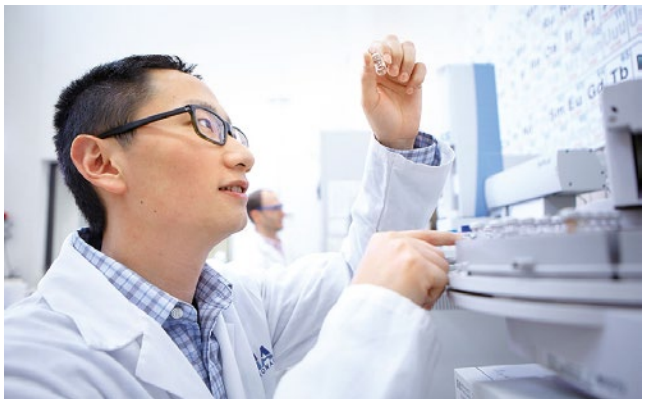
No Stranger to Awards

FONA has been recognized in 2016 as a Great Workplace in Manufacturing & Production in the Small & Medium Companies category, as evaluated via independent employee surveys conducted by the Great Place to Work Institute.

For the 11th consecutive year, FONA has also been awarded Chicago's Best and Brightest Company to Work For honors in 2016 by the National Association of Business Resources. FONA has won other national awards from the same organization for five years running, according to Tonya Hubartt, MS, FONA's human resources director.

In 2016, FONA won a "101 Best & Brightest Elite Award," the highest rating, specifically for Compensation, Benefits, and Employee Solutions. "We've received an elite award for 11 straight years, and in 2011 and 2014 we won Best of the Best, meaning we were ranked Number 1 in Chicagoland," Hubartt boasts. "These awards are a reflection of how FONA's 200-plus employees feel about FONA and our company's leadership under Joe Slawek."

Ask Slawek to share what he finds satisfying and rewarding about having a successful flavor company and he is quick to cite the human component. "For me, it always comes back to the people," he relates. "I really do find the people part of the flavor business most exciting. Being a people person, I enjoy interacting with our customers and with our FONA family members. The FONA people and our customers make this all worthwhile."



Chin-Ping Su, senior research and innovation scientist, FONA.

In January 2016 (recognizing performance from 2015), FONA launched a special and innovative Partnership Award Program with its vendors and customers.

"FONA initiated the award program as a way to recognize valued partners and their achievements," says Barb Pugesek, FONA's director of customer and culture excellence. "Categories include Speed & Service, Good Name & Reputation, Innovation, and Collaboration, among several others. FONA's third-party chemistry and microbiological testing laboratory was given the Quality & Safety Vendor Partnership Award."

Not only that, in June 2016, FONA hosted a Strategic Supplier Summit at its headquarters to communicate FONA's needs and goals to suppliers with a new, welcoming, transparent approach, which Pugesek says is atypical in the flavor industry.

"Suppliers spent a day at FONA, where they saw presentations and had one-on-one time with FONA leaders," Pugesek explains. "The group learned about FONA's founding principles, as well as the company's plans for the future. More than 60 vendors attended, with about half being raw material vendors. Other visitors included everyone from creative partners to uniform suppliers."

Slawek believes it's essential to build strong partnerships, whether within FONA or externally among customers. "It's a pleasure to join customers as they create successful, safe products that consumers will love," he elaborates. "When it comes to our people, it's thrilling to see them use their skills and talent, and watch as they come together and grow."

Favorite Flavor

"When people ask me what my favorite flavor is, I always joke, 'my favorite flavors are the ones that sell,'" Slawek quips. "Truly, it's a privilege to make a flavor selected to help power the preferences for a consumer brand. It's so exciting for me to see FONA create safe, high-quality flavors that truly fill a market need for our valued customers." ■

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

FONA INTERNATIONAL

Battling *Listeria* in Produce Processing

Sanitation best practices to ensure a pathogen-free environment | BY **ELIS OWENS, PHD**

Listeria-related outbreaks and recalls are a persistent problem for the produce industry, according to the CDC's listing of foodborne illness outbreaks and the FDA recall list. However, unlike other foodborne pathogens such as *E. coli* or *Salmonella*, which are usually brought into the plant on incoming raw material, *Listeria* can become resident in a processing facility, subsequently contaminating produce with each processing.

Listeria is a particularly challenging problem for produce processors. Much, if not all, of their product will reach consumers' plates without undergoing additional processing, such as cooking, that could kill pathogens. This ready-to-eat status requires that produce coming into the plant be free of contamination, and that processing is carried out in a manner that minimizes the potential for contamination.

Produce is frequently processed in facilities that are cold and wet, an ideal environment in which *Listeria* can become a persistent issue if cleaning and sanitation practices are not thorough and consistent.

Though seeming to be but an added cost to the food processor, effective sanitation can lead to long-term savings. Recalls are expensive, both in terms of lost product and in damaged brand reputation. A safe food product is a quality food product; no one wants consumers getting sick or sharing negative experiences. Additionally, the increasing involvement of the Department of Justice in outbreak investigations raises the potential for facility owners and management involved in outbreaks to become subject to criminal prosecution.

Proper sanitation, as a component of a robust maintenance program, can increase operational efficiency. Clean equipment breaks down less frequently, a sanitary environment increases product yield, and a cleaner workplace is safer for employees.

Components of Effective Program

Sanitary design of facilities and equipment is a major challenge for the produce industry. An effective program starts with a plant and equipment that can be cleaned properly. Oftentimes, equipment is not designed or built to be cleaned. Equipment may be made from porous materials that trap soil and bacteria. Floors may be in poor condition with eroded concrete or cracked and peeling epoxy coatings. These issues cannot be fixed overnight, but they need to be addressed whenever possible. Of course, sanitary design principles should be used for any new construction or equipment installation.

A detailed discussion of sanitary design is outside the scope of this article, but it is important to review the American Meat Institute Sanitary Equipment Design Principles. Here's a list of the 10 essential equipment characteristics:

1. Cleanable to a microbiological level;
2. Made of compatible materials;
3. Accessible for inspection, maintenance, cleaning, and sanitation;
4. No product or liquid collection;
5. Hollow areas should be hermetically sealed;
6. No niches;
7. Sanitary operational performance;
8. Hygienic design of maintenance enclosures;
9. Hygienic compatibility with other plant systems; and
10. Validated cleaning and sanitizing protocols.

It is vital to develop an operational cleaning and sanitation program. A master sanitation schedule must cover and document the following:

- What needs cleaning, with each item listed separately;
- How each item should be cleaned, including safety precautions such as lock out/tag out, how and what to dismantle (if necessary), what chemicals to use, how to mix and apply the chemicals, how to verify that the item has been properly cleaned, and how to sanitize the item;
- How often the cleaning should occur (e.g., nightly, weekly, or monthly); and
- Who is responsible for cleaning the item.

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For a successful sanitation program, an adequate number of properly trained personnel are needed. Sanitation professionals must be provided with ongoing training in effective and safe job performance. Also, adequate supervision is vital to ensure the job is properly completed.

The sanitation team needs the right personal protective equipment: rain suits, safety glasses, goggles, gloves, rubber boots, and hard hats/bump caps. The right tools are also key: wash-down hoses, foamers, buckets and scrub pads, flashlights, ladders to reach elevated equipment, measuring jugs for chemicals, and chemical test kits. Additionally, an abundant supply of potable water, at appropriate pressure and temperature, is critical to the endeavor—soft water is ideal but not essential.

The final and most important need is substantial time to do the job effectively. Most plants have a hard first shift start time, so it's important to instate a hard stop time. This allows the plant to be turned over to sanitation with enough time to effectively complete duties.

The sanitation process needs to be systematic. Once all the resources are in place, sanitation should follow a consistent pattern.

Dry clean-up/dry pick-up ("rough clean"). This cleaning preparation consists of removing all product and packaging materials from the area to be cleaned. All gross soil is swept, scraped, or otherwise picked up and placed into trashcans or other appropriate disposal containers. It is strongly recommended that select production personnel pick up gross debris and trash continually during production, minimizing the amount for sanitation. This is also a good time to manually clean sensitive electrical equipment with sanitizing wipes (or other low water cleaning methods) before covering them with protective plastic bags prior to sanitation. Dismantle necessary equipment at this stage, making sure appropriate safety precautions are followed to protect employees who are cleaning the equipment.

Pre-rinse/rough down rinse/wash down. Remaining debris should be washed from equipment using hoses, if possible, reusing water from flumes. Wash down is generally performed systematically, working from top to bottom and from the perimeter toward the center of the room. Inspect equipment to ensure it is ready for foaming. At this point, all gross debris should be gone.

Drains. Drains are a high-risk area for *Listeria*. It is recommended that drains be cleaned early in the sanitation process. This reduces the possibility of soil and bacteria transference from the drains to other surfaces while the drains are being cleaned. Sanitation professionals cleaning drains should have separate personal protection equipment and tools for this job that are color-coded to prevent them from being inadvertently used for other cleaning tasks. Weekly deep cleaning of drains with a drain foaming chemistry like from Sterilex Corp. is strongly recommended.

Chemical cleaning. To remove remaining soils, chemicals should be applied using either portable or wall-mount foamers. The foam allows the chemical to cling to the surfaces instead of immediately running off. As the foam breaks, the solution wets the surface and aids in the removal of soil. Self-foaming chlorinated alkaline cleaners are the most common chemicals used for sanitation. The chemistry used, however, should be selected based on the type of soils present and the material composition of the equipment. Mix chemicals according to the manufacturers' recommendations and the concentration titrated to ensure it matches the level specified in the sanitation program.

Hand scrubbing. The chemical, by itself, can only do so much; mechanical action is necessary for removing all soils from a surface. After the chemical has been sitting on surface for a few minutes, all surfaces should be scrubbed by hand using a scrub pad. All surfaces need to be cleaned, not just the direct food contact surfaces.

In many circumstances, additional chemical cleaning may be necessary. In hard water regions, periodic acid cleaning may be needed to remove hard water scale and mineral buildup. Other specialized cleaning protocols should be used to address specific cleaning challenges.

Rinsing. Use potable water to rinse away cleaning chemicals and soil *before they dry*. If the chemicals are allowed to dry, surfaces will need to be re-foamed before they can be rinsed properly. As with the initial wash down, rinsing should be performed systematically working from top to bottom and from the perimeter toward the center of the room.

Inspection of cleaned surfaces (re-clean if needed). After rinsing, all surfaces are inspected. If residual soil is found, the area should be re-cleaned as needed. In addition to visual verification of cleanliness, this is the appropriate point to use adenosine triphosphate (ATP) testing to verify the removal of soils from the surfaces. The results of ATP testing and the observations of the QA team should be provided to the sanitation team on a regular basis as feedback on their performance.

Sanitizing. When all surfaces have been cleaned and any required verification testing completed, the final cleaning and sanitation step begins—the application of sanitizer, an EPA-approved compound that is intended to kill all bacteria remaining on the surfaces. Many ready-to-eat facilities use a three-step process—disinfection, rinse, sanitize—for greater efficacy. A sanitizer is applied at a higher concentration, rinsing happens after appropriate contact time, and a no-rinse concentration is applied prior to starting production.

Sanitizers, applied at a "no-rinse" concentration, should be drained but not rinsed off the surfaces prior to the start of processing. Because some produce items can be damaged upon contact with certain sanitizers, it is essential that sanitizers be compatible with the products being processed. Furthermore, rotating, or changing, sanitizers on a regular basis is recommended to provide an additional challenge to resident microbes.

The steps described above can be applied to all produce processing facilities, whether they run conventional or organic products. Differences occur at sanitation step, where the final sanitizer must be one that is approved for organic production.

Listeria represents a growing challenge for produce processors, who are concerned about both their brand and their consumers' health. There is no single "silver bullet" that can prevent *Listeria* contamination on fresh produce. However, a robust cleaning and sanitation program with multiple interventions can allow effective control of *Listeria* in produce processing facilities. ■

Dr. Owens is the director of technical services at Birko in Henderson, Colo. Reach him at 800-525-0476.

Zika Virus and Mosquito Prevention

Managing mosquitos in and around food facilities to protect staff and customers

BY **STAN COPE, PHD**

We all know that a mosquito's buzz can bring down barbecues, camping trips, and little league games—but what about its effects on businesses? The important safety and health implications of these pests are too often overlooked in the context of work, even in the face of growing concerns about mosquito-borne illnesses. As issues like the Zika virus continue to make headlines across the country, food processing business executives and managers must think carefully about how they can mitigate mosquitoes in and around their facilities to ensure the well-being of their staff and customers.

What Are the Threats?

A major challenge that business owners have encountered in recent months is that of mosquito-borne illnesses—both in learning about these diseases and how they are spread, as well as keeping themselves and their employees safe. Business owners have a responsibility to ensure the safety and well-being of their employees, so it is important to understand how these risks can impact food processing facilities.

Recent headlines have been dominated by the Zika virus, a serious illness that has captured global attention. The virus was first discovered in humans in 1952 in Uganda, and has since remained relatively isolated to tropical communities. However, increased global travel has made it easier for infected individuals to carry the virus to new locales—and once it has made landfall in a new home, it can be spread through local mosquito-based transmission and other means, such as sexual contact.

The virus is mostly harmless to average individuals—it can cause mild symptoms such as fever, rash, joint pain, and conjunctivitis (pink eye)—but has also been closely linked to serious medical conditions including Guillain-Barre syndrome (a rare autoimmune disorder) and microcephaly among newborns whose mothers were infected while pregnant.

What Leaders Need to Understand

The Zika virus is primarily transmitted by infected mosquitoes from two distinct species—*Aedes aegypti*, the yellow fever mosquito, and *Aedes albopictus*, the Asian tiger. Both of these insects are particularly prone to spreading infection because they breed in close proximity to humans in artificial containers or other areas prone to holding water, even tiny amounts—from rooftop puddles to drainage dishes under planters. In commercial and industrial settings, such as food manufacturing facilities, it is critical to know that indoor water sources might provide mosquito eggs the environment they need to hatch, such as indoor trash receptacles or drainage areas.

> The challenges posed by mosquito-borne illness aren't limited to the Zika virus.

Another major consideration for business owners concerned about Zika is the time of day that these mosquitoes bite. Many individuals expect that mosquitoes will be present during evening outdoor activities, but *Aedes aegypti* mosquitoes are primarily active during the day and prefer to make their home in indoor environments—so workplaces could present a major opportunity for them to find their next meal. Business owners, particularly those in the American southeast where Zika infections through mosquito bite are forecast to most likely occur, should be aware of these distinctions to ensure that their anti-mosquito efforts are as effective as possible.

The challenges posed by mosquito-borne illness aren't limited to the Zika virus. The West Nile Virus, which has been present in North America since 1999, has made a recent resurgence in many U.S. communities, causing alarm among public health officials.

Because only certain species of mosquitoes can spread the Zika or West Nile viruses, try to communicate to employees effectively about the risk while not increasing worries beyond a reasonable level. Business owners who have questions about Zika or other mosquito-borne illnesses should work with a pest management professional in their community to learn more about which mosquito species are present in their area and how they might affect employees.

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What Should Managers Do?

Business owners should contact a pest management professional who can work with them to evaluate their situation, find areas of their facilities and surrounding grounds that might be serving as an ideal mosquito breeding ground, and develop a plan of action. Entomological experts can assess these areas and determine the best course of action, as well as provide strategic approaches that are best-suited to manage mosquito populations.

One example of a promising solution for food manufacturing facility business owners is Terminix's Attractive Targeted Sugar Bait (ATSB) mosquito service, which is non-toxic and safe for use in both residential as well as business settings. The active ingredient in the ATSB solution is garlic oil, which is combined with sugar from natural sources to attract mosquitoes and eliminate them before they can bite a human host. Because the solution does not include any chemicals, it is harmless to humans and pets, making it an ideal option for grounds around food manufacturing facilities. According to the company, ATSB has been shown to reduce mosquito populations by more than 90 percent in just three weeks.

Facilities managers can also take action themselves by conducting common-sense preventive activities. Facility owners should be mindful of opportunities inside and around their business for mosquitoes to breed, particularly by eliminating areas of standing water. Keep vegetation, such as plants, grass, and trees, well-trimmed to ensure that they are not creating ideal homes for these pests.

In addition to stopping mosquitoes from breeding, facility owners can mitigate the potential for mosquitoes to affect themselves and their staff. Employees working in outdoor areas or in facilities with mosquito challenges should wear long-sleeved shirts and long pants to prevent bites, and consider using an EPA-registered insect repellent containing DEET, picaridin, or oil of lemon eucalyptus. Business owners may also consider using box fans to keep mosquitoes away since they are relatively weak fliers and will find it difficult to land against the fan's gusts.

Keep vegetation, such as plants, grass, and trees, well-trimmed to ensure that they are not creating ideal homes for these pests.

Keeping the Bite out of the Bottom Line

Food manufacturing professionals and all business owners have a responsibility to ensure that they mitigate pest issues in and around their facilities for the health and safety of their employees and customers. To do so, they should talk to a pest management professional about the steps they can take independently, as well as advanced entomological solutions, that will address mosquito populations in a safe and nontoxic manner, particularly while remaining sensitive to the specific needs of food-related businesses.

To reduce the risk of infection for customers and employees, food manufacturing business leaders should implement the following tactics.

- Contact a pest management professional from a trusted provider to evaluate facility and grounds and identify mosquito breeding grounds and hotspots.
- Ensure that common-sense measures, such as eliminating standing water and keeping vegetation well-kempt, are implemented on a regular basis.
- Communicate efforts to employees and colleagues, and ensure they know steps they can take to protect themselves against mosquito bites, such as wearing insect repellent and long sleeved shirts.
- Ensure that any pest management strategies taken in food manufacturing facilities are nontoxic and safe for use around food. ■

Dr. Cope is the director of Entomology and Regulatory Services for Terminix International, a ServiceMaster company, and president of the American Mosquito Control Association. Reach him at SCope@terminix.com.

Knowing the Enemy

A key step in addressing mosquitoes in food processing businesses and facilities is understanding the pests themselves. Manufacturing business leaders often think of common pests, such as rodents, cockroaches, and ants, when considering risks to the health and safety of their facilities. Moreover, mosquitoes are also an important pest to keep in mind because of their propensity for spreading disease (and itchy bites) in residential and commercial settings alike. Get to know the enemy by reviewing the following facts.

- Mosquitoes are found in all sorts of habitats—they can be found on every continent except Antarctica. They thrive in damp environments because water is required for their eggs to hatch and the immature stages to grow, and they seek out cool areas that block the wind, such as plants and grassy areas. Food processing facilities can offer these types of environments due to the amounts of organic material and water found frequently in their business.
- These pests tend to be most active during warmer months and go dormant during the winter. However, anytime that the temperature reaches above 50° F, it is possible that mosquitoes will be out and about.
- Even if it seems like they're all out for blood, only certain species of mosquito are interested in biting humans—and of those species, only the females pose issues for humans. These pests need a blood meal frequently as a means to continue their reproductive cycle, while their male counterparts live off of nectar, plant sap, and honeydew.
- A mosquito can live anywhere from two weeks to a month or more, which gives them plenty of opportunities to find a human to bite and produce offspring.—*S.C.*

TERMINIX

Designing Meat Flavor and Texture

How to manage animal proteins to deliver the desired eating experience | BY JON A FALK, CFS

Textures and flavors are closely related, especially when animal protein products are concerned. The type of product you want to produce will determine not only the flavor, but the desired texture as well. For example, you would not want your hamburger to have the firm dry bite of hard salami and vice versa. Consumers understand the basic flavor of a hot dog, but add Chicago style and the concept changes drastically. Some products have a well-defined flavor, like a Sriracha meat stick, and some do not, like barbecue. When designing a new item, it is important to understand the interplay of ingredients and their impact on the texture and flavor of food items, since both qualities define the eating experience.

The Building Blocks

There are four components to any animal protein item: the protein itself, water, salt, and other non-meat ingredients.

Protein, the first component, can be factored by species, muscle selection, fat selection, and lean to fat ratio. In many cases, the first two factors are product driven. For example, ham comes from the hind leg of swine. You can buy turkey ham, and there the muscle selection and species are defined. With a ham, the developer determines the lean to fat ratio. It is desirable to have a fat cover on a bone-in-ham for baking but usually less desirable in a sliced deli ham for sandwiches. Fat amount and selection is very important as well. Pork belly fat is much softer and has a lower melting point than its back fat, making the back fat much more desirable in genoa salami in regards to particle definition and appearance. Fat is also flavor! Ever heard the saying "No waste, no taste?" Fat and water are key determinants of juiciness and mouthfeel.

This leads to the second component, water. According to the USDA Agricultural Research Service, lean muscle contains around 70-78 percent water depending on species and muscle selection. Formulating products with additional water has economic implications and affects the quality of the end products. In addition to affecting juiciness and mouthfeel, water facilitates flavors faster to the taste buds. Water may also be needed to help with mixing, emulsifying, and distributing other ingredients.

The third major component is salt. A preservative, flavor enhancer, and protein extractor, salt has many functional properties in animal proteins. How much salt is added, when it is added, the amount of physical action (e.g. mixing or tumbling), and time all affect the level of protein extraction, bind, and water retention.

The last component is other non-meat ingredients. These ingredients can be grouped as functional or flavor; though there's crossover between the two, ingredients generally fall into one or the other. Some common ingredients included in this last component are described below.

Phosphates can be a useful tool in making a juicy and flavorful food. In meats, phosphates have a breadth of function: they can increase water holding capacity, amplify ionic strength to allow actin myosin fibers to attract more water, improve stabilities of emulsions, bind divalent cations (Ca++, Mg++, Fe++), reduce oxidative rancidity, lower viscosity of meat, and have a synergistic effect with sodium chloride. They come in many different forms, but the most common is sodium tripolyphosphate.

Sodium nitrite is a key ingredient used in the meat industry, though its use is becoming less common. Nitrite is used when making a cured meat item. While naturally occurring ingredients exist for curing, sodium nitrite is the most popular. In many items, sodium nitrite is a required ingredient for both food safety and product identity.

Carbohydrates, including fibers, starches, gums, and sweeteners, assist with moisture management in meats by absorbing, immobilizing, or binding water. They are key additions for controlling texture and flavor. Sweeteners like sugar

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are typically used to sweeten and help balance flavors.

Finally, acids and bases affect pH balances in meats. In some products, such as pepperoni, lowering the pH is desirable. Lactic acid bacteria are added to pepperoni to lower the pH, which helps speed up drying and creates a desirable flavor. Other times, a lower pH can be harmful to the product for it can denature the proteins, causing poor yields and an undesirable texture. It is generally okay to add acids as a surface treatment, such as a lemon pepper pork loin rub, but if you're using it internally, some considerations must be made. Ingredients that buffer pHs like sodium phosphate, sodium bicarbonate, or the salts of organic acids can be used. It can be a tough balancing act, especially since the pH is a desired flavor component.

Another way of using an acid is to encapsulate them. The acid granule is coated with a hydrogenated fat that is solid at ambient temperatures. The coating will melt once a certain temperature is reached, usually between 140 and 155 degrees Fahrenheit. This allows for the addition of citric acid for flavor while avoiding protein denaturation. By the time the coating melts, the proteins will already be set and texture maintained. This practice of encapsulation can also be used for salt. For example, while developing a hamburger you want to avoid extracting the salt soluble proteins and limit the amount of bind, but you still want a salt savory flavor.

While encapsulations have great benefits, they do come with several processing issues. The coats are fragile and can be ruptured, thereby exposing the internal substrate and foil what you are trying to accomplish. When using an encapsulate, it is best to add it last into the mixing process, avoid any extreme physical action after its addition such as grinding, and get the item into its final form (sausage casing or mold) and cooked as quickly as possible.

The Taste

Flavor is an obvious and variable component when considering the eating experience of meats. Spices, whether whole, ground, or extract, are commonly used in the flavor systems of meats. In some applications, it is desirable to see the spice particulates, like fennel seeds in an Italian sausage or thyme leaves in a Cajun rub. These particulates add an appealing flavor, as well as visual and tactile experience. If particulates are aesthetically unappealing, fine ground spices or spice extractives can be used. Besides stable availability and cost, extractives pose a unique advantage: the ability to add a lot of flavor at very low quantities.

Non-meat additives and flavors are also widely used. Whether you're adding pistachio nuts to a mortadella or olives to a loaf, these additives enhance the flavor and visual appeal of a product. Sometimes just a flavor is needed, such as adding a dairy flavor to a cheddar bratwurst to bring out the cheese note.

There are several concerns when adding these adjuncts: they can add excess water to the formulation, bleed color, or even affect the pH. When using fresh or individually quick frozen vegetables, the moisture content needs to be considered. Therefore, a dried vegetable could make more sense. Additionally, if an item is acidic like a pickled jalapeno pepper, that acidity needs to be addressed by neutralizing and/or rinsing away the brine.

The Timing

When developing a desired texture and flavor, ingredients can and should be added in stages. For a sausage maker, adding the ingredients in stages is critical to the product's success. The salt, water, and phosphates get added early in the process with the lean portion of the meat block to extract proteins followed by the addition of flavor and fat parts of the block. Similarly, to make a hot ham, a neutral marinade of water, salt, and sodium phosphate can be injected into a ham muscle onto which a rub of red peppers and spices is added prior to stuffing into casings.

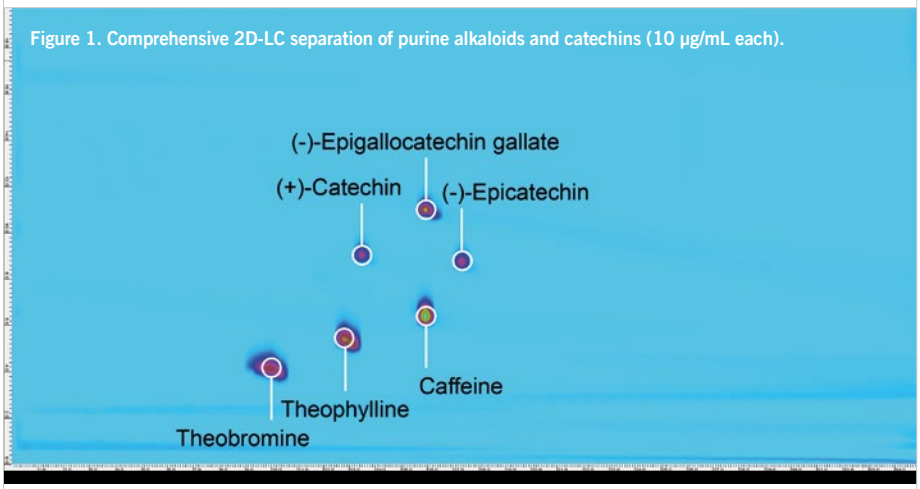
Entirely different flavor systems are used when dealing with whole muscle products versus ground products. While adding color and whole or ground spices into Italian sausage, an Italian pork roast will have very little flavor injected into it. If flavors are injected into the roast, they will be clear extractives to avoid tiger striping (where color is only in the path of the injector needles entering the muscle). In ground items, you have a lot more control over the bind of the meat product: fat levels can be adjusted to impact protein extraction levels; flavors can be more evenly mixed into the meat. Whole muscle products require more time and physical action to manipulate. Again, sodium phosphate can help by increasing the moisture uptake and juiciness of the finished product. Also, physically tumbling the muscle will help break down collagen and soften the tissue.

If flavors are injected into the roast, they will be clear extractives to avoid tiger striping (where color is only in the path of the injector needles entering the muscle).

When designing a new meat item, follow Stephen R. Covey's second habit from *The 7 Habits of Highly Effective People* and "Begin with the End in Mind." Understand what you want, even if you hand make it, design a gold standard, and then add ingredients that will help turn raw materials into the desired finished product. ■

Falk is the senior food scientist and meat specialist at Asenzya Inc. Reach him at jon.falk@asenzya.com.

Figure 1. Comprehensive 2D-LC separation of purine alkaloids and catechins (10 µg/mL each).



2D-LC in the Analysis of Tea: An Application Note

Comprehensive two-dimensional liquid chromatography to compare the composition of green and black tea

BY **JOHN LEE**

Tea is one of the most widely consumed beverages worldwide, particularly in China, where tea drinking can be traced back at least 1,500 years. Today, tea is the second most widely consumed drink in the world, after water.

The beverage is produced from the leaves of the shrub *Camellia sinensis*. Tea is harvested by plucking the bud and the first two leaves of this plant. Depending on the methods used to process tea leaves, three different types of tea can then be produced: green, oolong, and black tea.

Generally, after harvesting, the leaves are rolled, disrupting the cellular compartmentation and bringing phenolic compounds into contact with the enzyme polyphenol oxidase. In the production of green tea, the rolled leaves are steamed or dried immediately to inactivate the enzyme and minimize oxidation. In contrast, to produce black tea, the rolled leaves undergo oxidation (fermentation) before drying. Oolong tea is produced similarly to black tea, deploying a shorter fermentation period.

Tea has a highly complex chemical composition comprising diverse polyphenols, purine alkaloids, polysaccharides, amino acids, vitamins, lipids, and volatiles. The predominant polyphenols contained in green tea are catechins (flavan-3-ols) such as gallocatechin, epicatechin, epigallocatechin, epicatechin gallate, and epigallocatechin gallate. Epigallocatechin gallate is the most abundant catechin present in green tea. In the production of black tea, the monomeric catechins undergo oxidative polymerization to form the condensation products theaflavins and their polymers thearubigins.

Due to the complex composition of tea and the structural similarity of green tea phenolics, complete separation of the phenolic compounds in tea cannot be achieved using conventional one-dimensional liquid chromatography (1D-LC). However, separation power can be greatly increased using comprehensive two-dimensional liquid chromatography (2D-LC). 2D-LC is a technique in which two independent LC separations are applied to the sample. In comprehensive 2D-LC, the complete effluent following a first LC separation is injected onto a second column for further separation. This second dimension greatly increases the peak capacity and, as a result, the resolving power without increasing the analysis time.

Experimental Methods

Ten different samples of green tea and black tea were used for this analysis. Approximately 2 grams of the finely ground tea were extracted three times in acetone and water. The resulting extracts were each centrifuged to remove any particulate, and the resulting supernatants combined. A 100 microliter sample of this extract was then evaporated using a SpeedVac to dryness, and the resulting residue redissolved in 1 milliliter (mL) acetonitrile/water/acetic acid. The sample was then filtered before LC analysis.

LC analyses were performed using an Agilent 1290 Infinity II 2D-LC solution, deploying reversed-phase LC in both the first and second dimension. For this separation, an Agilent ZORBAX Eclipse plus C18 LC column was used for the first dimension and an Agilent Poroshell 120 Bonus-RP for the second dimension. Detection was achieved using an Agilent 1290 Infinity II diode array detector.

Method Validation

Figure 1 shows the separation of a 10 micrograms (µg) per mL mixture of the purine alkaloids, caffeine, theobromine, and theophylline as well as catechin, epicatechin, and epigallocatechin gallate. For this complex mixture, 2D-LC setup enables a complete separation of the purine alkaloids and catechins. In the first-dimension separation, a coelution of caffeine and epigallocatechin gallate is observed, which is resolved in the second-dimension separation. Deploying only the second-dimension separation, catechin and epicatechin would coelute. The precision of retention times and peak volumes were determined following multiple injections of this 10 µg per mL mixture of purine alkaloids and catechins. For these compounds, the second-dimension retention

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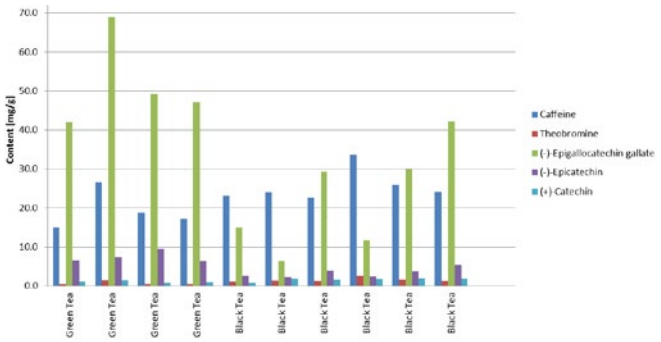
Graph 1. Quantification of purine alkaloids and catechins in green and black tea.



time precision was always below 2.5 percent and the peak volume precision was below 1 percent. These results demonstrated that the resolution and precision of 2D-LC is sufficient for the analysis of complex chemical compositions.

To quantify the levels of purine alkaloids and catechins in green and black tea, calibration curves were produced from each of the standard stock solutions. The response of caffeine, theobromine and theophylline, catechin, epicatechin, and epigallocatechin gallate at concentrations ranging from 2 to 100 µg per mL was measured. The coefficients of linearity produced for the purine alkaloids and catechins indeed achieved excellent linearity.

Green and Black Tea Samples

Theophylline could not be detected in any of the analyzed tea samples. In green tea, the epigallocatechin gallate peak shows at a much higher intensity compared to black tea. In black tea, there are several peaks detected at retention times between 30 to 32 minutes in the first-dimension that are not visible in green tea. These peaks could originate from theaflavins and thearubigins present in black tea.

Ten different samples of green and black tea were analyzed, and Graph 1 shows the quantification results for purine alkaloids and catechins. As expected, the green tea samples generally contain higher amounts of epigallocatechin gallate and epicatechin than the black tea samples. This difference is due to the longer fermentation period used in the production of black teas, in which the monomeric catechins undergo oxidation polymerization to form theaflavins and their polymers thearubigins.

Summary

This experiment demonstrates that a range of key phenolic compounds in complex tea samples can be separated using the resolving power of 2D-LC. This allowed precise assessment of the degree to which epigallocatechin gallate and epicatechin dominate in green tea samples compared to black tea samples. In comparison to 1D-LC, this 2D-LC approach revealed more information about the nature of black tea through the resolution of several peaks not significant in green tea. ■

Lee is global food market manager at Agilent Technologies, Inc. Reach him at john_lee2@agilent.com.

For complete article, go to www.foodqualityandsafety.com and type in "2D-LC in the Analysis of Tea" in search box.

In The Lab

RAPID METHODS

Rapid Microbial Detection Can Pay Big Dividends

Rundown on enhancements to culturing and alternative testing methods, as well as approaches to microbial testing

BY **PAUL R. MCCRIGHT, PHD**

As new regulations adopted under the Food Safety Modernization Act (FSMA) begin taking effect, more scrutiny is being placed on food growers, processors, distributors, and service providers to assure regulators and the public that their food products are free from pathogens that could cause foodborne illness.

On a daily basis, product contaminations are discovered by food processors. Companies in food service are also subject to problems involving foodborne pathogens.

Because FSMA requires food producers, processors, and service providers to certify that their products are free from pathogens such as *Listeria*, *Salmonella*, coliforms, and *E. coli*, obtaining results using valid pathogen testing protocols is now—and will continue to be—a necessary step for companies in all parts of the food industry.

Culturing and Traditional Methods

Culturing has been the traditional method of testing for presence of pathogens in food for more than a century. Requiring sophisticated medical-grade laboratories and highly-trained technicians, these tests are considered tedious and expensive. While culturing is moderately accurate, it's frustratingly time-consuming and, since only about 10 percent of all bacteria are able to be cultured, its applicability is limited.

"The majority of bacteria will not grow on nutrient medium in the lab," says Kim Lewis, professor of biology and director of the Antimicrobial Discovery Center at Northeastern University. He finds it fascinating that while the microbes continue to grow in nature, 100 years of effort to grow most bacteria in controlled settings has yet to prove successful.

On average, culturing takes between three and nine days to yield results, creating significant dilemmas for food producers. As a result, QA managers must determine whether the risks of keeping "good" product out of distribution for several days—pending results of testing—outweighs the risks associated with recalling product that might test positive for contamination later.

The *Biology Encyclopedia* states, "The limitations of cell culture include the finite doubling potential of most normal cells, the possibilities for unexpected infections with viruses or microorganisms, or even cross-contamination with other cell types."

Alternative Testing and Enhancements to Culturing

Several enhancements to culturing have been developed. A Fourier transform using infrared spectrometry speeds up the time-to-results to approximately 20-24 hours, however, this new and improved method can only test for a limited number of microbes.

Growth-based carbohydrate utilization tests provide results based on changes to a culture caused by a microbe digesting sugars contained in the culture media. These tests can provide results within two to 72 hours. A wide range of bacteria as well as some yeasts and molds can be tested with these methods.

Polymerase chain reaction (PCR) tests are the most common alternative to traditional culturing, however, they also rely on culturing as a step in the process. PCR tests are available for the major foodborne bacteria, but generally require between one and five days to provide results. Advanced PCR tests include quantitative tests and real-time tests.

Raman Spectroscopy Imaging relies on the molecular vibration of a sample to scatter laser light into patterns that are unique for each microbial species. It requires the previous mapping of scattered light patterns, a concentrated sample, and specialized equipment operated by a well-trained technician. Raman spectroscopy may be combined with viable staining techniques and can provide results in a matter of minutes. A limited number of prominent bacteria have been categorized.

Ribotyping uses restriction enzymes to digest the DNA in bacteria, creating fragments that can then be hybridized, digitized, and analyzed by comparison with reference organisms in a database to determine the species present. These tests take approximately eight hours to yield results and can be applied to a wide group of bacteria.

Low-cost test strips are available for most major foodborne microbes and pro-

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vide results within a few minutes when the test strip is dipped into a sample solution. Quick solution test kits are available for identification of certain pathogens. Drops of a sample are placed into a certain test solution, which will change colors in the presence of the pathogen. Unfortunately, test strips and quick solution kits are susceptible to contamination during testing and are not highly accurate. Due to accuracy issues, providers of such kits recommend a secondary culturing or PCR test to confirm results, thus incurring major delays in the time required for a definitive result.

The Rapid Testing Methods

Rapid microbial testing platforms that use fluorescent DNA markers to identify species power some of the most advanced technologies currently in operation. Using combined scientific methods and well-established microbiological techniques, these systems can be automated as well as mobile—in some circumstances. Some of these culture-independent platforms use fluorescent in situ hybridization, fluorescent microagglutination, and filter cytometry to identify the pathogens rapidly. Some systems can do so in as little as two hours. Using such methods, in combination with others, can yield very accurate results and effectively eliminate the need for expensive labs and highly trained technicians. Quantitative data and detection of dead microbes are also possible using such rapid testing methodology.

Different test methodologies have a variety of advantages, disadvantages, and limitations. The primary factors that determine the overall desirability of a test methodology are the speed of obtaining results, the accuracy of results, the breadth or robustness of the test, and the associated costs of the tests.

When producers are quickly assured of the safety of their products, they can put them into the market immediately, thus obtaining maximum product shelf life and bringing in maximum revenue. When product batches test positive for an unwanted pathogen, a quick test result allows the company to withhold product from distribution, effectively preventing exposure to the public and the need for costly recalls.

In addition, rapid identification allows firms to take immediate action to limit exposures and/or problems associated with microbiological contaminations. The source of the problem can be found quickly and action can be taken to eliminate further contamination from that source. Better public relations are maintained, legal and financial liabilities are minimized, and the company's long-term reputation is enhanced.

Food growers, manufacturers, and food service providers must meet these new requirements from FSMA. Finding the best techniques for identifying contaminated food products and sources of contamination is vital to all companies in this competitive and highly regulated industry. ■

Dr. McCright is the executive vice president and project manager at Biotrack Diagnostics Inc., working with Biotrack's rapid microbial testing technology. Reach him at pmccright@biotrackdiagnostics.com.

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Fundamentals of Viscosity in Quality Control

Viscometers are essential tools for obtaining rheological measurements | BY ROBERT MCGREGOR

Viscosity measurement is a universal necessity in QC labs throughout the food industry. If the item in question can flow, you can bet that there is a test method specified by R&D for viscosity. This requirement ranges from "thin" fluids, like milk and canned soups, to "average viscosity" soft solids, like salad dressings and yogurts, to "thick pasty" or "hard" materials, like peanut butter and cheese. Given the wide variety of food types that may need to be measured, choosing the proper viscometer can be daunting.

Viscometers are relatively basic instruments that measure torque using a rotating spindle immersed in the material. Resistance to spindle rotation is the physics that constitutes the basis for viscosity measurement. Continuous contact with the material is necessary to provide a steady torque signal. Mathematical calculation converts the torque reading into a viscosity value with established scientific units: "centipoise" (cP) in the U.S. and "milliPascal-seconds" in Europe and Asia.

Pre-Test

Normally R&D will specify the viscosity test method and the recommended instrument. This is based on evaluation testing by R&D to characterize the food item for its flow behavior. The following are important questions that must be answered.

1. How much of the food material is available for testing? Is there any limitation in the available quantity?

2. What type of spindle is needed to test the material?

3. What is the appropriate torque measurement range for the instrument?

4. Is temperature measurement or control needed for the test?

5. How long does the spindle rotate in the material before taking the reading?

Sample size for the viscosity test is not usually an issue for food manufacturers. There is more than enough material available in most cases. If temperature control of the sample is required, then working with a small sample size is preferable in order to minimize the time needed to achieve equilibration.

One important consideration that affects the test is the type of container holding the food item. If the test is performed in a standard 600 milliliter (mL) lab beaker, then there is no issue; if performed in the container that packages the item, then volume of material available for testing may affect the choice of spindle.

Spindles

Various spindle types used for viscosity measurement appear in Figure 1 on p. 42. Most common are the first two which are either cylindrical in design or have a disc near the bottom of the shaft. The cone spindle is ideal for very small sample size (less than 2 mL) while the SC4 type requires 16 mL or less. T-bar is used with paste-like materials. Vane can measure mixtures with suspended solid particles as well as thick pasty substances. Spiral is appropriate for simulating processes that use augurs to move material. Fortunately, spindles aren't expensive and can connect interchangeably to any standard benchtop viscometer. Initial choice is most likely cylinder or disc, but could transition to one of the others for reasons indicated.

Torque

Torque range for the viscometer is chosen based on the expected viscosity range for the food material. Most common choices are "LV" for "low viscosity" or "RV" for "regular viscosity," also referred to as "medium viscosity." "HA" and "HB" cover the high viscosity range, but are much less frequently selected. However, the chocolate industry has elected to standardize on viscometers with "HA" torque.

The maximum torque that can be measured for each range is as follows:

LV = 673 dyne · cm
RV = 7,187 dyne · cm
HA = 14,374 dyne · cm
HB = 57,496 dyne · cm

The minimum torque recommended for use in each case is 10 percent of the maximum. Therefore, LV range goes from 67.3 to 673 dyne · cm (centimeter) and RV from 718 to 7,187 dyne · cm. The theoretical viscosity values that can be measured with each are very broad, ranging from under 10 cP to over 1 million cP. Practically speaking, LV is typically used in the range from

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1 to 100,000 cP while RV is used from 100 to over 1 million cP. Because the overlap in range coverage is significant, there is another consideration that determines which one to select.

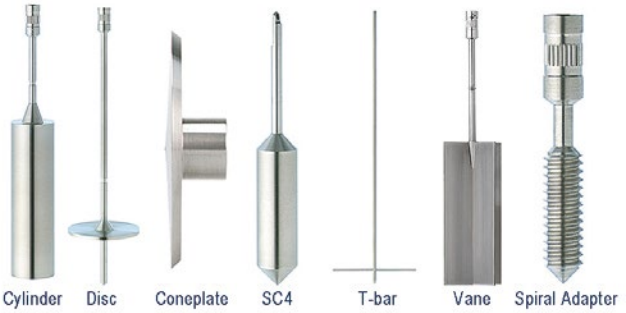
Measurements

The combination of spindle and rotational speed determines the precise viscosity range that can be measured. Viscometer manufacturers provide this information in tables for easy lookup. Viscosity measurement is oftentimes targeted to fall in the middle of the torque range—around 50 percent on a scale of 0 to 100 percent. This provides flexibility for possible variance in measurements that may occur from batch to batch during production.

Temperature measurement is easily accomplished during the viscosity test. Today's instruments can be ordered with built-in temperature probes. The display on the instrument reports the viscosity in cP, torque in percentage, and temperature in degrees Celsius or Fahrenheit. Best practice is to record the temperature and viscosity readings together, since viscosity will change inversely relative to variances in temperature. If temperature control is required, then use of a bath is likely. A key decision is whether to immerse the sample in the bath or use circulation to an external fixture designed to hold the sample while temperature equilibrates.

Don't forget to consider time of spindle rotation for the viscosity test method. QC's objective is to make the measurement as quickly as possible. Some food materials exhibit decreasing viscosity as the spindle rotates. This behavior is called "thixotropy," which is sensitivity to shearing action versus time. In this case it is important to establish the time interval for making the viscosity measurement.

Figure 1. Types of Spindles.



AMETEK BROOKFIELD

Obtaining a clearly defined test method from R&D guarantees that QC's job will execute successfully. Discussion with instrument manufacturers will ensure that the proper viscometer model with the appropriate accessory equipment is chosen within the budget available for the job. ■

McGregor is director of Global Marketing/High-End Lab Instrument Sales for AMETEK Brookfield. Reach him at bob.mcgregor@ametek.com.

Rendering for Clemens Food Group's new pork processing facility in Coldwater, Mich.

Engineering Considerations for Your New Plant

Manufacturers, contractors, and suppliers/vendors must work together to ensure construction goals and food standards are achieved | BY **TYLER CUNDIFF**

The food and beverage industry has experienced significant changes and advancements in the past several years. From regulations to technology and automation capabilities, the industry is being faced with new challenges. But, these challenges also lead to opportunities.

In fact, according to Dublin-based market research company Research and Markets, the food industry is expected to bring in $3.03 trillion in revenue by 2020.

What's Driving Food & Beverage Market Growth?

Growing consumer demand and the rise of new types of requirements both domestically and internationally are largely driving these changes. Manufacturers recognize the need to update their operations to meet these demands and want to integrate flexibility, efficiency, and automated technology into all their processes. These demands have also paved the way for financing to become more readily available to companies.

The implementation of the Food Safety Modernization Act (FSMA) is also a factor contributing to food and beverage market growth since companies must ensure their operations accommodate the new policies. As a result, many manufacturers are finding it more cost-effective to build new facilities instead of renovating their current operations.

In sectors such as U.S. protein, there is also significant growth as offshoring poses a growing number of challenges. Pennsylvania-based Clemens Food Group is designing and building a new pork processing facility in Coldwater, Mich. that is expected to process 10,000 hogs each day.

Mergers and acquisitions have always played an important growth role in the food industry, and recent years have held many of them. Brands such as Tyson Foods and Hillshire Brands merged, and Mars, Inc. acquired Proctor & Gamble's pet food business. Kraft and Heinz also successfully completed their merger to form the Kraft Heinz Company, a transaction that created the fifth largest food and beverage company in the entire world.

When these deals take place, business strategies often change as well. Sometimes, the new business plan recommends new construction as opposed to working through the process of combining operations. For example, after acquiring Chicago-based Wrigley in 2008, Mars, Inc. expanded its existing manufacturing plant in Illinois to add the production of Skittles to its operations.

Last but certainly not least, the U.S. continues to attract food and beverage manufacturers for multiple reasons including its energy resources, its marketplace stability, and its workforce.

How to Make the Growth a Reality

Before food companies embrace growth in the form of new greenfield facilities or expansion projects, several considerations must be made; the most important is the critical control points (CCPs), the heartbeat of the food manufacturing process. As food safety is the foremost motivation for a food and beverage facility, all manufacturers have in place critical components that guarantee their brand's commitment to food safety and quality. For some, this may be a certain piece of equipment that is central to all food preparation; for others, it might be the workers and their performance in producing a perfect product.

CCPs must be clearly defined and understood by all engineering, design, and construction partners before moving the first pile of dirt because they drive the design-build process. This understanding helps define the quantity and quality of products produced in a unit of time, how big the warehouse must be, how often the manufacturer ships products and receives raw materials, how many docks are needed, how the process flow should be developed, and how the layout should be positioned. It's a process that begins at the goal and meticulously takes steps

(Continued on p. 44)

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backwards to fully realize the project and bring it to fruition.

If this type of project is approached as just a building with concrete and steel, a vital area could be missed. What's more, a manufacturer's food safety and quality could be compromised. The new build or expansion is much more than a box—it's where food or beverages that reach thousands are created and packaged, which is a serious and humbling endeavor that must be felt by the contractor and the manufacturer.

How Engineering Dictates the Design

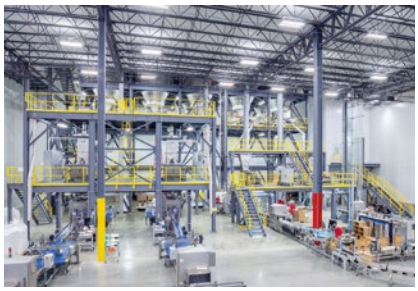
For food and beverage facilities specifically, the engineering of a new build or expansion project often drives the design. One of the first areas to consider is the site—a critical part of both greenfield and brownfield projects. For greenfield, civil engineering studies of the land must be performed to determine any potential issues with drainage or other environmental concerns. The site must also be examined for growth potential to ensure it can accommodate future expansion, which is also a proponent for brownfield projects.

Additionally, food facilities often require a high utility and electricity demand, which makes it imperative that the local municipalities and utilities can meet these requirements.

Before the design can be fully embraced, the manufacturing process has to be laid out and optimized from an equipment adjacency standpoint, particularly by defining the automation elements at play. Automated processes frequently lead to stronger safety and quality as well as increased speed to market, thereby allowing food manufacturers to stay competitive and relevant. For food and beverage companies, the following automation elements often get integrated into new or existing facilities:

- Product distribution/clean-in-place (CIP) networks via mix-proof valve clusters;
- CIP and clean-out-of-place systems;
- Grain handling, milling, and packaging systems;
- Packaging and palletizing systems;
- Sampling and package inspection systems;
- In-line blending system to replace manual batching system;
- Powder into liquid addition system to replace manual bag dumping; and
- Product quality and process monitoring systems and equipment.

Automation can also be delivered in the control systems of a manufacturing facility. For example, Canadian-based Champion Petfoods recently opened its first U.S. operation called DogStar Kitchens, requiring a highly innovative automation system to control its kitchen's productions. For this particular project, the engineering team began with a supervisory system. Champion embraced the system wholeheartedly and wanted it to control every automated aspect of the kitchen. The system, affectionately called Window into the Kitchen (WINK), does, in fact, control and automate everything from track and trace capabilities and recipe management to product sampling and data collection. WINK ensures consistency in food production to meet Champion's food safety and quality standards.


Design of Champion Petfoods' operation.

Security is a big aspect of WINK: a particularly high focus is put on protecting recipes. The system was developed to include remote access for users anywhere with an Internet connection. While this provides excellent flexibility, it does create security risks. To hedge against these risks, the team developed single sign-on functionality to better control users. One of the unique aspects of DogStar Kitchens is its stringent dedication to produce foods that go beyond FSMA and European Union requirements for human foods. In lieu of such standards, the security of the kitchen, too, has been said to be equivalent to that of a hospital. Champion Petfoods now wants to integrate WINK into all its kitchens and future endeavors.

Why Communication Is Vital

After these processes are determined, the architect must establish how the building can circumscribe all these elements. Designers must consider high-level master planning concepts and the details of a specific building component within each room. The fit and finish of individual rooms is determined by the risk associated with the task performed in each room.

The engineer must also consider expandability options both from an interior and exterior point of view—if there is room for the operational staff and maintenance, and how cleaning systems can be incorporated. For a period of time, the envelope is constantly shifting: structure and design are contingent on the communication between the engineer, designer, and manufacturer.

Once the envelope is sealed, the structural engineering team comes in to execute the task. Mechanical and electrical engineering teams follow to supply heating, venting, air conditioning, lighting, and other systems. Next, the process and mechanical engineering teams come in with steam utilities, compressed air, and other necessities that directly tie to the production of the facility.

To deliver the principal food safety goal for manufacturers, construction aspects must be considered as well. For instance, the life cycle cost of the building and the maintenance and sanitation of building components are some factors that need be considered when selecting construction materials. In addition, jobsite cleanliness is a crucial part of safety throughout the life of the new build or renovation.

As these steps take place, constant communication between the various movable pieces and parts must occur. Innovative technologies, such as 3D printing and virtual reality, have proven to be effective communication tools for design-build contractors to illustrate each and every detail of the project. The manufacturer, the contractor, and the suppliers and vendors must work together as one cohesive team to ensure all goals are met, and ultimately, to secure food safety and quality. ■

Cundiff is director of business development at Gray Construction, an engineering, architecture, and construction firm that has designed and built nearly 1,000 manufacturing facilities, including food and beverage, across the U.S. Reach him at tcundiff@gray.com.

GRAY CONSTRUCTION

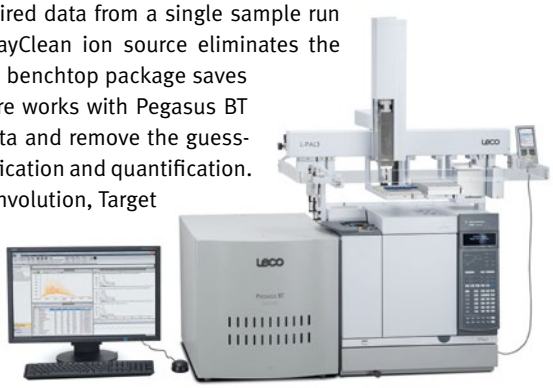
NEW PRODUCTS

QC Testing

UV-BioTAG is a line of bacterial reference strains containing green fluorescent protein markers. It cultures visibly fluoresce under UV light, making them easily distinguishable from natural contaminants isolated from food samples. *E. coli* O157:H7, *Shigella flexneri*, *Salmonella* Typhimurium, and *Salmonella* Senftenberg are the first strains available. UV-BioTAG is offered in two formats. The UV-BioTAG Vial Kit contains six vials of six individually packaged lyophilized microorganism pellets, which are rehydrated in a sterile fluid and then plated on growth medium. The UV-BioTAG Swab Kit contains six all-in-one devices, featuring a lyophilized microorganism pellet, ampoule of rehydration fluid, and a swab that allows for direct inoculation of growth medium. **Microbiologics, Inc., 800-599-2847, www.microbiologics.com.**

GC Time-of-Flight Mass Spectrometer

The Pegasus BT gives users required data from a single sample run with a TOF-MS platform. The StayClean ion source eliminates the need for source cleaning, while a benchtop package saves space. ChromaTOF brand software works with Pegasus BT to automatically process user data and remove the guesswork involved with analyte identification and quantification. Features include NonTarget Deconvolution, Target Analyte Find, library searches, an easy-to-configure interface, and data that provides a complete mapping of each sample. **LECO Corp., 269-985-5496, www.leco.com.**



Rapid Protein Test

AccuClean Advanced determines the cleanliness of food contact surfaces and equipment. Cleanliness is determined by detecting any protein residues left behind from previously processed food and liquids. The 10-second visual test reveals detected protein residue through an easy-to-interpret color change. If no protein is detected, the solution in the bottom of the cup will remain copper-colored to indicate the surface is clean. A color change to gray indicates low level protein has been detected, while a change to green/blue or blue indicates a higher level of protein detected. Protein detection limit is 15 µg/mL. **Neogen Corp., 800-234-5333, www.neogen.com.**

Water-Based Mycotoxin Test Kits

AgraStrip WATEX extended line of water-based mycotoxin test kits enable the testing for multiple mycotoxins from the same sample extract. Test kits are available for aflatoxins (B1, B2, G1, G2), deoxynivalenol, and zerealenone. Tests for total fumonisins and ochratoxin A are in the final stages of development. All test kits come with Whirl-Pak bags that contain integrated filter membranes so there is no need for additional extract clarification equipment. **Romer Labs, www.romerlabs.com.**

In Other Product News

SGS's Analysis of Mineral Oil Components in Food helps identify mineral oil hydrocarbons and separately measure mineral oil saturated hydrocarbons and mineral oil aromatic hydrocarbons levels.

ANSR for *Campylobacter* is the fifth test available for **Neogen's** ANSR pathogen detection system, providing results after only 18 minutes of reaction time following sample prep.

GOJO expands PURELL products into the surface disinfecting and sanitizing category for food service.

3M Food Safety's Petrifilm Lactic Acid Bacteria Count Plates provide an all-in-one solution, eliminating the need for anaerobic equipment.

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