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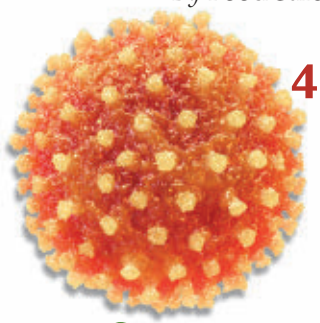

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Editor's Letter

Ushering In a New Tradition

By the time you read this, more than 2 months will have passed since the very first World Food Safety Day on June 7. But since it fell after our last issue went to press, please allow me a slight diversion to reflect warmly on that day for me.

It began 3 weeks earlier with an invitation from Claudio Andrade, plant quality & food safety engineer, at Stonyfield Organic in Londonderry, New Hampshire. They were planning to celebrate World Food Safety Day and wanted to bring in an outside speaker to give a talk on the topic of food safety.

Honored to be asked, I made the short drive north from central Massachusetts on June 7 and was welcomed by the quality team. After touring the plant and learning about the company's passion for their food safety processes, everyone (Stonyfield employees and invited guests) was invited to the cafeteria to have lunch and hear about food safety. Together with Colleen Smith and Chuck Metcalf from the NH Department of Health and Human Services, we talked about the importance of the food safety culture from the top down (management to consumer) and the pertinent regulatory issues affecting Stonyfield's particular industry (dairy). It was rewarding to see scientists and nonscientists alike participating in the event: A great group from human resources even talked about how they play a role in food safety! It was a great day, and I left inspired by this company's passion for food safety and the integrity of their products.

While food safety is something to focus on *every* day, the chance to come together, share best practices, and showcase our food safety heroes *does* deserve some extra attention, because as we know, doing the hard work of food safety is often under-appreciated. And while we're at it, National Food Safety Education Month (September) is right around the corner. Thanks to all of you who make safe food for everyone, everywhere.

Best Regards,

Barbara VanRenterghem, Ph.D.
Editorial Director

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Kottapalli Joins FSM Board

Balasubrahmanyam (Bala) Kottapalli, Ph.D., has joined the *Food Safety Magazine* Editorial Advisory Board. Bala is currently the director of enterprise microbiology at Conagra Brands in the Food Protection and Regulatory Affairs Division. Prior to joining Conagra, he worked as a senior scientist at Kraft Foods in the Food Safety & Microbiology Division from December 2008 to April 2012. He also worked as a microbiologist/lab manager at the Institute for Environmental Health Inc. in Seattle for 4 years.

Bala obtained his Ph.D. in food safety and an M.Sc. in cereal science from North Dakota State University. He also has a master's in applied statistics from Penn State University. He obtained his B.Sc. degree in dairy engineering/technology from Osmania University, India. Bala is an appointed member of the National Advisory Committee for Microbiological Criteria for Foods and has completed ASQ Certified Quality Engineer certification requirements.

EFSA Identifies Food Safety Research Priorities for the Next 5–10 Years

The European Food Safety Authority (EFSA) recently announced a set of food safety research priorities the agency plans to focus on for the next 5–10 years.

The plans—laid out in an article titled "Food Safety Regulatory Research Needs 2030" and published in the *EFSA Journal*—look at how research can stimulate innovation and how science can be communicated effectively to society. They also considered issues such as the provision of safe food for a growing world population. The authors' recommendations will inform EFSA's research agendas and strategy.

The three overarching research streams will be:

- Safe Food Systems: Improve food safety while moving toward alternative and sustainable production systems
- Innovation in Risk Assessment: Anticipating the impact of innovations and new technologies on integrated risk assessment
- Holistic Risk Assessment: Understanding the context, delivery, and communication of impactful science.

The article can be read online at EFSA.europe.eu.

ONLINE & OF NOTE

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With the near-constant attention paid to leafy greens of late, we review the California Leafy Green Products Handler Marketing Agreement, which was created following the tragic spinach outbreak of *Escherichia coli* in 2006 that sickened over 200 people. The program's goal is to ensure safe leafy greens and confidence in produce food safety programs.

General Mills Presented with Coveted Black Pearl Award at IAFP 2019

The International Association for Food Protection (IAFP) presented General Mills with the prestigious Black Pearl Award at this year's IAFP Annual Meeting in Louisville, Kentucky. The Black Pearl Award is given annually to a single company for its efforts in advancing food safety and quality through consumer programs, employee relations, educational activities, adherence to standards, and support of the goals and objectives of IAFP. General Mills works with farmers to source raw materials, produce food across more than 100 brands, and distribute that food to customers in retail, e-commerce, and convenience and foodservice settings, landing in homes across 100 global markets. General Mills also makes it the company's business to strengthen its communities and the planet. With 38,000 employees, the company believes in using its size as a force for good, and it is doing so by advancing sustainable farming, combating climate change, fighting hunger, and supporting local schools. General Mills is the parent company of many popular household brands, including Cheerios, Yoplait, Häagen-Dazs, Pillsbury, and Betty Crocker.

New FDA Draft Guidance: Improving Seed Safety

The U.S. Food and Drug Administration (FDA) recently released a proposed draft guidance, *Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting*, intended to make the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) aware of the agency's serious concerns with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly cooked sprouts.

Incorporating aspects of the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Annex II, Annex for Sprout Production; the International Sprout Growers Association-Institute for Food Safety and Health's U.S. Sprout Production Best Practices; and Good Agricultural Practices, FDA's draft guidance provides the agency's recommendations to firms throughout the production chain of seeds for sprouting. It states that if a grower, holder, conditioner, or distributor reasonably believes that its seeds are expected to be used for sprouting, FDA recommends that the grower, holder, conditioner, or distributor take steps that are reasonably necessary to prevent those seeds from becoming contaminated. FDA also recommends that firms throughout the supply chain–from seed production and distribution through sprouting–review their current operations related to seeds for sprouting.

By George G. Misko, Esq.

U.S. and EU Approaches to Defining and Evaluating Impurities and NIAS in Food Contact Materials

Current regulations for food contact substance purity

Expressions of concern about impurities in food contact materials have increased over the last few years. While general safety requirements for food contact materials exist in both the United States and the European Union (EU), neither jurisdiction has issued official guidance or regulations pertaining to the manner in which these impurities [better known as nonintentionally added substances (NIAS) in the EU] are evaluated and permitted in food packaging and other food contact materials. The existing regulatory requirements in the U.S. and EU that impact NIAS and impurities in food contact materials are discussed below.

U.S. Requirements

In the U.S., the U.S. Food and Drug Administration (FDA) imposes suitable purity requirements for food contact substances. These requirements are found in the Good Manufacturing Practices (GMP) regulations for food contact substances, which state, in part: "Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use."[1] Accordingly, a substance can be found to comply with a relevant food additive regulation but still be unsuitable for food contact use if, for example, it contains an unsafe level of impurities or imparts an off taste or off odor to the food.

As a result of the GMP regulations, all foreseeable impurities based on the manufacturing process–such as residual monomers, starting reactants, aids to polymerization, catalysts, and products of incomplete reaction–should be considered. Importantly, oligomers are considered part of polymers in the U.S., not impurities. This is in contrast to EU law, but more on that later.

With respect to food contact substances cleared as indirect food additives and listed in Title 21 of the *Code of Federal Regulations* (C.F.R.), the regulations will occasionally specify limits for expected impurities. For example, this is the case with polynuclear aromatic hydrocarbon limits in high-purity furnace black.[2] It is important to keep in mind that while most FDA regulations concerning food contact materials do not prescribe specific manufacturing processes, manufacturers must ensure that an indirect food additive is suitably pure under GMP regulations, even if limits for impurities are not specified.

Substances cleared through a food contact notification (FCN) also must meet suitable purity requirements. However, since their clearance is specific to the substance made by the process described in the FCN, any changes in the manufacturing process require a new purity assessment to determine whether there are additional impurities or an increase in the level of any impurity. If the changes in the impurity profile are substantial, a new FCN may need to be submitted.

In its Chemistry Guidance for submitting an FCN,[3] FDA recommends that submitters include detailed information on the intended use and stability of a food contact substance during the intended use conditions, along with a thorough description of possible degradation products and intermediates.

European Union Requirements

The EU also requires that food contact materials and articles be manufactured in compliance with GMPs. This entails ensuring that food contact materials, under normal or foreseeable conditions of use, do not "transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof."[4]

The term "NIAS," as used in the EU, is defined in the Plastics Regulation, (EC) No. 10/2011, as: "[A]n impurity in the substances used or reaction intermediates formed during the production process or decomposition or reaction products." Therefore, residual monomers and aids to polymerization are not NIAS since they are intentionally added. In contrast, the following are considered NIAS: impurities in monomers and additives, reaction intermediates, breakdown products of aids to polymerization, and oxidation byproducts formed by the reaction of package components with exterior oxygen.

Ironically, oligomers are now considered incomplete products of the reactions used to form polymers and, therefore, reaction intermediates (i.e., NIAS). This reasoning seems consistent with recent European Food Safety Authority (EFSA) opinions suggesting that oligomers are not covered by the monomers listed in the Union List in the Plastics Regulation. However, it seems paradoxical that the only part of a polymer that is actually measured in migration studies and assessed for toxicology purposes is no longer considered a part of the polymer and is now judged no more than an impurity.

The preamble to the Plastics Regulation provides more information on NIAS and how they are regulated. NIAS include impurities in substances used in the manufacture of plastic materials or articles originating from their manufacturing or extraction process (recital 18) and degradation products formed during the manufacture and use of plastic materials and articles (recital 20). The regulation also specifies that if any of these substances are relevant for the risk assessment of the main impurities of a substance or the main reaction and degradation products of the intended application of a substance, they should be included in the specifications and/or restrictions of that substance. Furthermore, these substances may be present in the final material or articles but not included in the Union List. However, if a migration limit for a NIAS is set in the Union List, it must be met.

Evaluation of Impurities to Assess Safety

For the producer of food packaging,

or a food packer, to ensure that impurities or NIAS meet safety requirements, a risk assessment may be in order. This can be challenging since, as mentioned above, there are no defined methods for evaluating NIAS. However, several guidance documents have been published that offer some clues on how to conduct risk assessments of NIAS in food contact materials and articles, including ones from the International Life Sciences Institute Europe[5] and PlasticsEurope.[6] However, the recommendations in these guidance documents are not legally binding. Therefore, internationally recognized principles of risk assessment may be relevant for these evaluations.

> "As attention on impurities in food contact materials continues, regulatory requirements on how they are evaluated may be on the horizon…"

In general, the information useful in conducting a risk assessment is: (1) the chemical identity and structure of the substance; (2) exposure information; and (3) toxicological safety data. The requirements for determining exposure and conducting the safety evaluation vary between the EU and the U.S. These differences are discussed below.

Chemical identity and structure: The first step is to determine the chemical identity and structure of the NIAS or impurity. This can be based on knowledge of the starting substances or the chemical process, or a search of the literature.

When the identity of a NIAS cannot be determined, an analysis of the substance may be required. This can involve complex testing by multiple methods, such as gas chromatography, high-performance liquid chromatography, nuclear magnetic resonance, and mass spectrometry. It is important to keep in mind that it may not be possible to detect or identify some impurities using existing analytical techniques.

Exposure assessment: The initial step in estimating exposure is to determine the potential extent of migration of the impurity into food. This can be based on data obtained through migration testing using food simulants or food. Since factors such as the type of food (aqueous or acidic, for example) and conditions of duration and temperature of a material in contact with food can impact migration, they need to be considered in protocol design. Additional factors such as the type of packaging material (e.g., film, coating, or rigid article) and the presence of a functional barrier will dictate sample preparation as well. As an alternative to conducting studies, exposure may sometimes be sufficiently established through the use of worst-case assumptions or diffusion modeling.

Once the level of migration is determined, dietary intake can be estimated. In the EU, this may be done using a default assumption for surface-area-to-food volume of 6 dm^2 per 1 kg food, a body weight (bw) of 60 kg, and daily food consumption of 17 g food/kg bw (or 1 kg food/60 kg bw).[7]

Rules for determining exposure to food contact substances in the U.S. are different from those in the EU. In the U.S., dietary exposure is established using migration data and consumption factors (CFs). CFs represent the ratio of the weight of all food contacting a specific packaging material to the weight of all packaged food consumed.[8] An exception exists for infant formula since it may account for 100 percent of an infant's diet; therefore, packaging materials used to hold infant formula likewise account for 100 percent of the CF.

FDA also has developed food-type distribution factors to account for the difference in migration rates that can occur with different types of food (e.g., aqueous, acidic, alcoholic, and fatty) and the types of materials in which they are usually packaged. Differing from Europe, FDA recommends a surface-area-to-food-volume ratio of 1 square inch of surface area to 10 g of food.

Safety evaluation: The safety evaluation involves the identification of adverse toxicological effects or hazards associated with an impurity or NIAS, followed by defining the critical dose or exposure level of that substance in the daily diet (below which the impurity or NIAS is not expected to pose a risk to human health). The first step should be to ascertain what evaluations have already been completed on the substance, such as by EFSA, the UN Joint Expert Committee on Food Additives, FDA, and others. The second step is to review toxicity studies that may have been completed after the evaluation; if no authoritative evaluations have been completed, a search of the literature is necessary.

For NIAS with unknown toxicity but known structure, the threshold of toxicological concern (TTC) can be applied. The TTC is a screening tool that allows for a qualitative risk assessment and prioritizing substances for toxicity testing. The TTC assesses whether a substance is likely to be of concern based on its structure and the estimated exposure. EFSA published a new guidance on the use of the TTC approach in food safety assessment in June 2019.[9]

If none of the options mentioned above apply, toxicity studies may be in order.

In the EU, once it has been determined that a NIAS does not pose any concern with regard to genotoxicity and sufficient chronic or subchronic toxicity data in the form of animal studies are available, a tolerable daily intake (TDI) can be calculated. According to PlasticsEurope's guide on risk assessment of NIAS, the TDI for a food contact material in the EU is typically calculated by dividing the no-observed-adverse-effect level obtained from an oral subchronic (90-day) study by a safety factor of 100.

In the U.S., FDA applies a tiered approach to the *(continued on page 57)*

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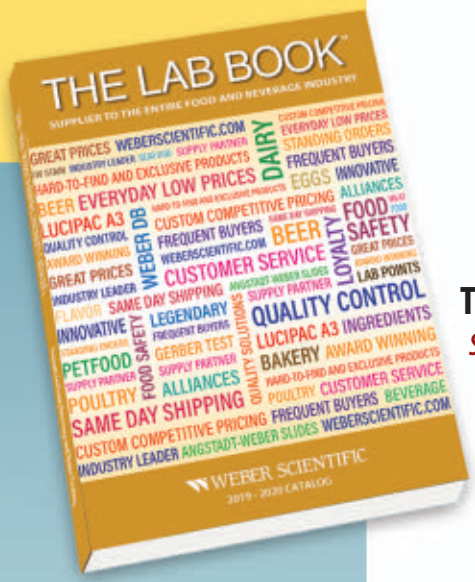

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By Barbara Kanegsberg and Ed Kanegsberg, Ph.D.

The Importance of Cleaning for Food Safety

Critical cleaning in food processing

In food safety, cleaning and sanitation become a single concept, a single thought process. It is easy to lose sight of the function of cleaning as distinguished from disinfection. Without appropriate cleaning, effective disinfection can be difficult or impossible to achieve. Cleaning hard surfaces associated with food processing is becoming increasingly challenging. It is instructive to focus on the role of cleaning hard surfaces as a distinct activity. While this discussion emphasizes the cleaning of food contact surfaces and transfer lines, the principles also apply to noncontact surfaces.

Understanding Soil

Soil is matter out of place. Soil can be alive, dead, biological based, or nonbiological. Soil may be organic (carbon based) or mineral based with no carbon. Soils may be introduced inadvertently through air or mists, or people can introduce soils. A soil may have been an essential part of the process that, if it remains on the surface, becomes a liability.

Many soils are associated with food processing. Common organic soils include carbohydrates, proteins, fats, and petroleum. Soils can come from lubricants and greases used in food processing equipment. Metalworking fluids and lubricants can be petroleum based or bio based, and/or may be complex, proprietary mixtures of organic and inorganic material. Inorganic soils in food processing include salts, water stone (calcium nitrate), food stone (e.g., calcium oxalate), and metallic deposits like rust and oxides from processing equipment. Timmerman[1] describes many soils commonly found in food processing. Residues of cleaning/disinfecting agents are also soils. A comprehensive list of soils depends on the specific situation. It is therefore appropriate to consider the food processing application and determine all potential soils and residue that might impact the food.

Critical Cleaning

Cleaning is physically removing soils, not killing or inactivating or denaturing soils. Appropriate cleaning is required to manufacture medical devices and computer hardware. Cleaning product contact surfaces is essential in pharmaceuticals and paints.

Effective food processing requires critical cleaning. Critical cleaning is not necessarily more cleaning. Too much cleaning is costly in terms of supplies and labor; after a certain point, the cleaning process can damage product-contact surfaces. Manufacturers sometimes refer to precision cleaning as an ultimate goal. Precision cleaning involves setting up a strict written protocol and then never deviating from it. While a cleaning protocol is important, it is not a complete solution. The protocol must be effective. It is not unknown for cleaning to be performed the same way over and over, yet that cleaning is determined to be incorrect or ineffective.

Critical cleaning is value added. It is cleaning that, if eliminated, unacceptably raises the risk of harming the product. A critical cleaning process involves using a scientifically based, defendable protocol at the correct point(s).

Cleaning Is a Process

Effective disinfection starts with cleaning. Cleaning is a process, not just pouring a chemical onto a surface, wiping it around, and declaring that the surface has been cleaned, disinfected, and sanitized. There are three steps in a complete cleaning process. The first is washing. The function of the wash step is to ensure

that the cleaning agent makes contact with the soil on the surface, to remove soil from the surface and keep it away from the surface. The next step is rinsing. Thorough rinsing is essential to remove the cleaning agent; it may also continue the cleaning action. Drying, the third step, removes water and volatile residue.

TACTful Cleaning

Cleaning processes involve TACT: temperature, action, chemistry, and time. In general, higher *temperatures* promote cleaning effectiveness. For every 10 °C increase in temperature, the reaction rate doubles. *Action* is the physical force that promotes soil removal. Two examples of action are high-pressure spray and elbow grease. Cramer[2] describes the function of the *chemical* components of cleaning agents. Terms like *emulsification*, *saponification*, *peptizing agents*, and *dispersive agents* translate to a host of chemical ingredients, not all of which are listed on the safety data sheet. The correct *time* is required at the wash, rinse, and dry stages. The temptation to decrease cleaning process time is pervasive through many industries. For this reason, cleaning processes have to be not only clearly defined but also documented and monitored.

More is not necessarily better. Cleaners should be used at recommended dilutions. There have been instances where employees have poured cleaning concentrate directly onto surfaces. Some cleaners can be more effective at removing soils when they are diluted. Using excessive cleaner can make rinsing difficult. Those who formulate chemistries for cleaning and disinfection are put in a bit of a catch-22 situation. From an environmental and economic standpoint, concentrated products are a great idea. Shipping concentrate has a smaller environmental footprint; less packaging is needed and less water means lower cost per pound. However, if employees decide that more product means better performance, the concentrate may be wasted, and the process may be compromised.

Compatibility and Coordination

The cleaning process must not damage the work surface. It would be unacceptable for the cleaning process to increase surface porosity because soils could become entrapped and more difficult to remove. Materials compatibility issues are a potential problem with any cleaning process, because a process that effectively removes soil could interact with the surface. With repeated cleaning cycles, aggressive cleaners can damage food contact surfaces. Thus, regular inspection of such surfaces is crucial.

Cleaning must be coordinated with disinfection. Life requires water, the correct atmosphere, a favorable temperature, an appropriate amount of time,

and a supply of the right food, at the correct acidity or alkalinity. Life is persistent and inventive. Therefore, cleaning and disinfecting should be designed and tested relative to the application.

Tackling Residue

Achieving critical cleaning in food processing also includes understanding what makes soils stick. Factors include temperature, physical forces, chemistry, and time—the same TACT factors that are involved in cleaning.

> "Cleaning processes involve TACT: temperature, action, chemistry, and time."

The residue to be removed is not always the same as the original soil. Altered soils are often much more difficult to remove than the original material. Temperature can chemically modify soil. For example, sugar is relatively simple to remove from a hard surface. However, adding heat to simple sugars produces caramel. Caramel consists of thousands of complex compounds[3] that are far more difficult to remove than sugar. Physical forces can also result in more adherent soils, in part by driving soils into hard surfaces and changing the nature of the soil. This can happen even with careful selection of food processing equipment. If soil, including food residue, is allowed to remain on surfaces, it becomes more difficult to remove. Time and exposure to air and moisture can change the soil. In explaining the importance of prompt cleaning to those involved in other industries, we often use the example of how much more difficult it is to clean a lasagna pan that has been left on the counter overnight. The time between processing and cleaning should be minimized.

Difficult Soils

Some soils are inherently more difficult to remove than others. Among more classic soils, Timmerman points out that, for example, carbohydrates tend to be more readily removed than denatured protein.[1]

Botanicals are often difficult soils to remove. As foods become more sophisticated, it is inevitable that we will see greater cleaning challenges in food processing. Materials like vitamin K can adhere to analytical equipment; if cleaning is difficult in the analytical world, it ought to raise a red flag in food processing. The Agriculture Improvement Act of 2018 removed hemp from Schedule 1 of the Controlled Substances Act of 1970 and implemented new provisions for hemp production.[4] Processing cannabis edibles involves removing soils that are very adherent to hard surfaces. Even if the material is removed promptly, more complex cleaning processes have to be developed. The surface may be successfully disinfected, but it may not be clean enough. Particularly with cannabis processing, the philosophy of cleaning needs to move more toward that used for pharmaceuticals and perhaps even into a specific category. Dedicated processing equipment is prudent. However, using dedicated equipment does not eliminate the need for carefully defined cleaning processes.

How Clean Is Clean Enough?

In food processing, a clean surface is often taken to mean "visibly clean." What does "visibly clean" actually mean? It's a subjective concept, and it is one that has been successful historically. For many applications, it may not be necessary to use complex analytical techniques to demonstrate clean. At the same time, it is appropriate to demonstrate, define, document, and illustrate visibly clean surfaces in the context of your food processing requirements. A picture is worth a thousand words. Demonstrations are better; hands-on exercises are better still. During employee training, it is reasonable not only to show cleaning techniques but also to illustrate what a clean surface ought to look like. Depending on the processing equipment, the process might call for required lighting to view the surface and areas of the equipment to be inspected. Cleaning process documents are easier to understand when they include photographs of a clean surface and one that is not clean.

Visual cleanliness of food contact equipment may not be sufficient, because some residue may have a clear or glass-like quality. UV light and/or ATP (adenosine triphosphate) may reveal previously hidden soils. Are all surfaces visible? Process equipment may require partial disassembly for cleaning. Documentation of the procedure for disassembly (and reassembly) and specific cleaning requirements, including process and frequency, must be specified. Cleaning protocols may have to be validated by appropriate cleanliness testing or surface testing methods that would not be practical to use on an ongoing basis. In such instances, a strategy such as periodic surface monitoring, using contact angle determination, may be appropriate.

How clean is clean enough? The rule in 21 C.F.R. Part 110 includes Good Manufacturing Practices.[5] The guidance is general, the bottom line is "clean enough." This means as a manufacturer, you have to justify and demonstrate with defendable methods what is clean enough.

Cleaning difficult soils in food processing is not restricted to cannabis processing; the botanical example points to the importance of cleaning as distinguished from disinfection. Effective cleaning means that residue from one batch of food does not interfere functionally or aesthetically with subsequent batches. If residue from one batch impacts the appearance, texture, taste, or odor of subsequent batches, there can be adverse economic implications aside from safety factors, even if sanitation is achieved. Therefore, it is important to be on the lookout for interfering residue from all sources, including cleaning/disinfecting agents themselves.

Soil residue combined with subtle damage to process equipment impacts

more than food aesthetics. Buildup of residue makes disinfection more difficult and could also support development of biofilms.[6] Biofilms are designed to survive, in part by creating their own protective armor. Although food processing facilities are designed to discourage development of biofilms, scrupulous attention to the cleaning process is essential.

Training and a Food Safety Culture

Consistent, effective cleaning is not likely to happen without effective employee training and without monitoring employee performance of the cleaning tasks. Training should include education and is most effective when it is a two-way street. One reason is that cleaning is in part cultural. Developing company values where food safety is an inherent part of corporate culture is essential.[7] We all probably learned how to clean from family and community practices. Some in industry assert that workers of a particular ethnic background are always going to clean improperly and that you can't teach "them." In our experience, most of us have the capacity to learn. Time invested in training programs that include not only the rules but also the reasons behind the rules is time very well spent. In fact, a team approach that includes feedback from employees about the required cleaning/sanitation processes can be an illuminating approach to food processing. That feedback can also improve process performance and save money. Getting feedback means making sure employees are actually telling you what's going on, that you actually hear their suggestions, and that you listen. An unresponsive "command and control" approach often covers up cleaning problems. A collaborative approach solves problems. ■

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Barbara Kanegsberg *and* ***Ed Kanegsberg, Ph.D.****, are industry leaders in critical and industrial product cleaning at BFK Solutions LLC.*

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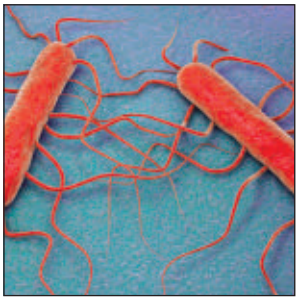
By Samuel D. Alcaine, Ph.D.

Keys to Effective Monitoring for *Listeria*



Knowing what to look for—and where—in the processing plant

The Food Safety Modernization Act was passed nearly a decade ago, and as of last year, all food processors are required to be compliant with the act's Preventive Controls for Human Foods regulation. Being compliant involves performing, under the guidance of a preventive controls-qualified individual, a Hazard Analysis of the facility, ingredients, process, and products; defining the appropriate preventive controls for the identified hazards with the relevant recall plans; and verifying the implementation of those controls and plans. For ready-to-eat (RTE) food processors, for whom contamination of the food by the bacterial pathogen *Listeria monocytogenes* from the environment is a likely and foreseeable hazard, this has meant developing and implementing pathogen environmental monitoring (PEM) programs as part of their sanitation controls.[1] For many RTE processors, this can seem a daunting undertaking, and even for processors with established PEM programs, ensuring that those programs are effective is a daily challenge. Do not despair; with diligence, training, and a proactive attitude, you can build and maintain an effective PEM program.

What Is *Listeria monocytogenes*?

L. monocytogenes is a Gram-positive, rod-shaped bacterium. *L. monocytogenes* has been isolated from the pristine soils of the Catskill Mountains to the bustling sidewalks of New York City; it is ubiquitous in our environment. *L. monocytogenes* is not the fastest grower and does not do well competing with other bacteria. Unlike many bacterial competitors, though, *Listeria* does grow well in the cold and even better when that environment is also wet and filled with nutrients. When we think about our RTE processing areas, we remove *L. monocytogenes* and the competition with each cleaning and sanitation cycle. We then keep the environment cold to maintain product quality, and when we start processing, we create a wet and nutritious situation that is ripe for any *L. monocytogenes* lurking in hard-to-clean places or hitchhiking on an employee's shoe. This is why hygiene and sanitation programs are so important for controlling routes of transmission into our processing environments, and why PEM programs are critical to helping us root out *L. monocytogenes* within the processing environment.

L. monocytogenes is one of 17 species in the genus *Listeria*, which includes *L. innocua* and *L. cornellensis*. These other species grow well under the same environmental conditions as *L. monocytogenes*, making them useful for identifying areas that could support the unwanted pathogen. Thus, many PEM programs use microbiological tests that look for the entire genus to find potential problem sites before they provide harborage to *L. monocytogenes*.

Building a PEM Program

One of the foundational steps of a PEM program is classifying the processing environment into zones in relation to the proximity and risk of contamination to the food being made. Typically, we break our processing environment up into four zones: Zone 1 comprises food contact surfaces—any piece of equipment that comes in contact with the food. Zone 2 consists of nonfood contact surfaces near the food or food contact surfaces—things like the underside of tables, the exterior of processing equipment, control panels, and refrigeration units. Zone 3 encompasses

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Salt is salt, right? Think again.

It's reasonable to believe every container of salt contains just what's on the label. It's even more reasonable to believe that, in today's food-safety conscious world, the salt we buy — and put in and on our food — is pure, safe, and has gone through rigorous quality control.

Consumers, restaurants, food processors, and wholesalers are often unaware that their salt contains unwanted impurities. The worst offenders are importers that sell unprocessed Himalayan salt.

There is a loophole that many in unscrupulous importers use to sell salt that is not food grade and will never be properly cleaned or inspected before it is delivered to your facility. This is because salt can come into the country with, at most, a glancing inspection as a bulk ingredient destined for further processing but never receives the proper and necessary processing. The salt on your store shelf, in your facility or in your private label product could contain contaminants from rocks/clay to metal bits to other foreign matter.

Most importers do not know how to properly clean their Himalayan salt and are not in compliance with GMP (Good Manufacturing Practice) safety and quality standards. Some of it is downright filthy. Often, such impurities are readily detectable by the naked eye with opaque and off-color bits of foreign matter.

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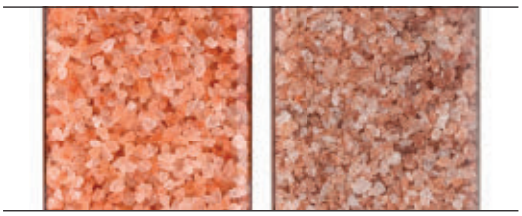

Optically Clean® Not Clean

Himalayan salt that contains foreign material is much more susceptible to a recall. It is the buyer's responsibility to be aware of exactly what is in their salt. When buying Himalayan salt, be vigilant, be aware and ask questions. Take a close look at the salt – Is it clean? Is it food grade?

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QUESTIONS TO ASK YOUR SALT SUPPLIER:

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2. Are they registered with the FDA and in compliance with new FSMA regulations?
3. Is their salt Organic Compliant?
4. Is the facility third-party audited and by what certifying body?
5. What other food safety certifications do they hold?

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more remote nonfood contact surfaces located in or near the processing area—drains, walls, floors, forklifts, carts, and air vents. Lastly, zone 4 takes us outside the processing area, covering nonfood contact surfaces in locker rooms, offices, shipping docks, maintenance areas, and other storage areas. The majority of swabs will be focused on the high-risk zones, but all zones must be monitored to understand where *L. monocytogenes* is harbored in the facility. Sometimes, assigning a surface to a zone takes extra attention. For example, the frame of a specific piece of process equipment when the food safety team is passing through at the end of the day may look like a zone 2, but if observed during processing, it would be noted that condensate forms on the frame and drips onto exposed food or a food contact surface, and thus is also actually a zone 1. Likewise, drains directly under food contact surfaces may be classified as zone 2 rather than zone 3 to account for the proximity and risk to the food during processing.

> "...*Listeria* does grow well in the cold and even better when that environment is also wet and filled with nutrients."

Processors will need to select sites for testing and ensure that each site has a clear descriptor and ID so that they can be consistently tracked. To select these sites, the team of employees responsible for the PEM will need to walk through the processing facility with an eye out for potential harborage sites and areas of high traffic. It is also important to do multiple walk-throughs at different times of the day to not miss any important changes or conditions. The goal is to think like *L. monocytogenes* and look for places that are protected from cleaning, are potentially kept cold and wet, and have leftover "food." At the end of this exercise, the food safety team should have a master list of all the possible sites. The question of how many sites a processor should have really depends on the size and condition of the facility and equipment. It's not unheard of for a midsize facility to have identified upward of 500 sites. Keep in mind that all the sites on the list do not need to be tested at the same time, and the list itself should not be written in stone. The employees responsible for testing should have the freedom to add sites that appear during their rounds, like if they spot cracks on a piece of equipment or an unexpected backup in a drain. The master list also must be regularly reviewed and updated whenever new pieces of equipment are added or old ones discarded, as these events can not only introduce new harborage sites but also could change the site's zone classification.

Once all the sites are mapped out, it's time to start implementing a swabbing regime. Common questions are: how many swabs should a processor perform, when should they be done, and how often should they be taken? The common response is that it depends on the risk. Just like when identifying the sites, the number of processing lines, condition of the facility and equipment, traffic flow, and frequency of operation all factor into the equation. The U.S. Food and Drug Administration (FDA)'s current draft guidance *The Control of* Listeria monocytogenes *in Ready-To-Eat Foods*[2] recommends that even the smallest RTE processors swab at least five food contact surfaces and five nonfood contact surfaces per production line. Ideally, these swabs are taken 3 to 4 hours into the production run or just before the end. This provides the best opportunity due to the time, temperature, and available nutrients for *L. monocytogenes,* if it's lurking, to grow to levels where it can more readily be detected. As for frequency, large operators may be swabbing weekly, whereas small processors operating only a few days a week may be able to justify a less-frequent regime. There are reasons to swab at different times; for example, to verify the efficacy of your cleaning and sanitation, or to evaluate whether certain events like construction or weather-related damage have changed the potential distribution of *L. monocytogenes* in your facility. The point is to be proactive in the search for *L. monocytogenes* so you are not surprised later.

You Found a Positive; Now What?

The common adage about *L. monocytogenes* is "If you haven't found it, you're not looking hard enough," which means you will get positives from time to time. Do not freak out; have a plan for how to address it. Documented deep-cleaning procedures for an area that tests positive are key, as is following up with more frequent monitoring of that site to ensure that whatever action was taken was sufficient to remove *L. monocytogenes.* If additional or intermittent positives occur at a given site, vector swabbing is a valuable practice to help identify the true source of contamination. Vector swabbing involves adding swab points to the area around where the positive site is located. This could be nearby drains, overhead pipes/ceiling, wall/floor junctions, feet/undersides of equipment, or nearby foot-traffic areas. For example, a floor drain may intermittently test positive, and one might think the drain itself is the hard-to-clean harborage site, when in fact the true source is a crack where the floor meets a structural column a few feet away. The crack is hard to see by the cleaning crew, it traps food particulates, and it doesn't dry rapidly. When *L. monocytogenes* levels get high enough and the column gets wet, it disturbs the harborage site, releasing *L. monocytogenes* into the environment and down the drain where the swabbing program can detect it. Vector swabbing can help processors identify these problem areas, allowing for corrective actions to be identified, like sealing the crack, thus removing the harborage point and correcting the problem. It is important to document these correc-

tive actions for positive sites, and if a problem persists, do not be reluctant to ask for outside help. There are private consultants and university food safety Extension professionals who either have the needed expertise or know someone who does in your facility's food production category and can help you root out the problem.

Swabbing programs looking for the presence or absence of *Listeria* help identify harborage spots, but there is always the challenge of figuring out whether what appears to be intermittent positives are due to transient *L. monocytogenes* hitchhiking on a random employee's shoe or are a deeper, more persistent problem that you only occasionally catch a glimpse of. The cost of DNA-based detection methods has dropped significantly in the past 5 years, and performing whole-genome sequencing (WGS) of environmental positives to develop molecular fingerprints so that processors can compare isolates is no longer out of the question. Soon it may become routine. In our previous vector-swabbing example, WGS of the positive isolates could allow a processor to confirm that the *L. monocytogenes* strain found at the column was the same as that found in the drain and feel confident that the problem was addressed correctly. If the strains turned out to be different, it would help the processor realize there were multiple problems to address rather than being caught by surprise later. Using WGS over time, processors can build a catalog of all the *L. monocytogenes* strains they encounter and see if certain strains turn out to be persistent problems in the environment; if so, added steps may be needed to address the problem. This may seem like extra credit, but it's important for processors to think about how they can incorporate strain tracking into their PEM programs. Just this spring, FDA revisited an RTE processor and sent a warning letter stating that their procedures were inadequate to significantly control *L. monocytogenes* in their facility. FDA justified this not only because their visits had found multiple environmental positives over the past 3 years, but also because WGS had shown that the same strain was present over several years. Thus, the processors had not effectively removed a resident pathogen that had also matched a clinical isolate from someone who had been sick. Managing a PEM program that incorporates WGS is not simple, but building those capabilities is a prudent exercise for RTE processors looking to protect their consumers and their business.

Conclusions

PEM programs that effectively control *L. monocytogenes* are not built overnight. They begin with written Good Manufacturing Practices, then implement hygiene and sanitation programs and proactive PEM swabbing programs. They require a commitment to review, interpret, and respond to the data. These programs cannot be built by a single person alone; they require teams of individuals from across departments and levels within the facility, as well as members from outside the business. As RTE processors start or strengthen their current programs, they should remember there are resources to help. Regional food safety Extension specialists are just an email away for advice, and there are PEM training programs available at academic institutions across the country, like here at Cornell University, plus industry-specific organizations like the International Dairy Foods Association. Ideally, working together, we can build industry-wide PEM programs and practices that support the health of both consumers and our businesses. ■

***Samuel D. Alcaine, Ph.D.**, is an assistant professor in the Department of Food Science at Cornell University.*

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By Bob Ferguson, Strategic Consulting Inc.

The FSMA Intentional Adulteration Rule Is Here: Are Processors Ready?

Ready or not, the IA rule is just around the corner

Food Safety Insights is a collaboration between Food Safety Magazine *and the food safety market experts at Strategic Consulting Inc. to bring you the latest market research, insights, and trends in food safety, analytical testing, diagnostics, laboratory services, sanitation, and related topics in quality and safety testing, and assurance in the food and beverage industry.*

Three years ago, as part of their rulemaking under the Food Safety Modernization Act (FSMA), the U.S. Food and Drug Administration (FDA) published their final rule requiring food processors to address hazards that they may be facing from threats caused by acts intended to cause wide-scale public health harm. The rule, titled "Mitigation Strategies to Protect Food Against Intentional Adulteration," otherwise known as the FDA Intentional Adulteration rule (IA rule), was designed to address and prevent intentional attacks on food, as would be the case in a terrorist attack, which are solely intended to cause widespread illness and death and erode confidence in the safety of our food supply.

Food facilities will need to conduct a vulnerability assessment and develop plans to prevent or minimize the risk from threats to their food operations. The first compliance date (for the largest facilities with more than 500 employees) was July 26, 2019. FDA has said that they will begin enforcement inspections starting in March 2020. Additional compliance dates for smaller facilities will follow in July 2020 and July 2021.

As the first compliance date is now here and with others approaching, we wanted to find out more about the state of readiness of food processors for this new FSMA requirement and what difficulties and challenges they are seeing with implementation. So, Food Safety Insights asked more than 300 processors–235 in the U.S. and Canada and 80 international companies–about their state of readiness for the IA rule and heard about what they have done, what they may have left to do, and what they see as their biggest challenges.

We first asked whether the processors felt they were generally ready for IA rule implementation. In general, we saw a high percentage of companies reporting a high level of confidence that they are in compliance with the rule. As can be seen in Figure 1, 88 percent of those companies in the largest category in the U.S. and Canada report that

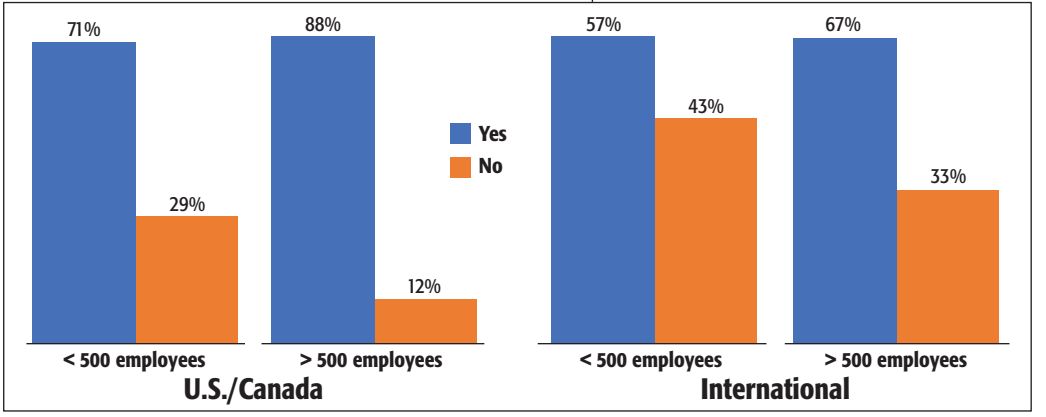

Figure 1. Is your facility ready for the FSMA IA rule?

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they are ready. Processors in our sample of international companies reported a somewhat lower number of companies confident in their readiness, but nonetheless, more than two-thirds of those affected by the July 2019 date reported being in compliance.

Interestingly, more than one-half of all the larger processors (both U.S./Canadian and international processors) who say that they are in compliance indicated that they have been ready "for some time now." Also, when we only look at smaller companies with a compliance date not coming until 2020 or 2021, 71 percent of these in the U.S. and Canada and 57 percent of the international processors indicated that they are also ready now. These data indicate that many processors have been preparing for these compliance efforts and are not panicking at the deadline.

Based on the comments we heard, however, this indication of a high level of readiness may prove to be deceptive, and some companies may be in for a surprise. More than a few respondents mentioned that since they maintain a third-party certification–with several mentioning Safe Quality Food, British Retail Consortium, or International Organization for Standardization–they had confidence that their programs will be in compliance. Others mentioned that they are dual-regulated facilities (FDA/U.S. Department of Agriculture), Canadian Food Inspection Agency–regulated facilities in Canada, or other national regulatory bodies cited by the international processors, and the inspections that they receive from these other agencies will suffice to test their programs for IA compliance. Compliance with these requirements, of course, does not equate to compliance with the FSMA IA rule, and the companies holding these opinions will quite likely find out that they have work to do.

So, companies in our survey are generally reporting that they think they are indeed ready for their upcoming compliance dates. But what did it take for them to get there? What have they seen as their most difficult challenges? We asked those questions.

For processors in the U.S. and Canada, the number one issue that they reported was related to the details of compliance with the rule and the corresponding documentation (Figure 2). As with our previous surveys about other aspects of FSMA, many companies believe that they have compliant programs, but they will not know until they have their first inspection and hear the results and interpretations from FDA. One processor had a comment that was typical of many: "We have our program in place and we think we are in compliance, but we are waiting to make sure that we have what they want." Others commented that without the still-anticipated FDA guidance documents, Food Defense Plan Builder software, and the availability of final compliance training programs, they are put in a position to guess what specifically is needed, and they may find on the day of their first inspection that they have more work to do. All of this concern is also wrapped into a general uneasiness about whether they have the proper documentation needed. As we've heard in the past with other FSMA issues, processors separate the actions they are taking to comply directly from the documentation of those actions. And, while they are confident that they are taking the right actions, they will not know for sure about the compliance of their documentation until they have an official inspection and the regulators confirm that they have "dotted all of the i's and crossed all of the t's."

Their second-most-mentioned concern was related to how far they need to go to address each risk scenario. Processors are looking for guidance on which risks are most likely and need to be prioritized versus those where risk scenarios are sufficiently unlikely that they need not be addressed in their programs. Several processors mentioned that they were very aware of the risks presented by the potential actions of a company insider. These people have the most access to food and food processing operations, and this access gives them

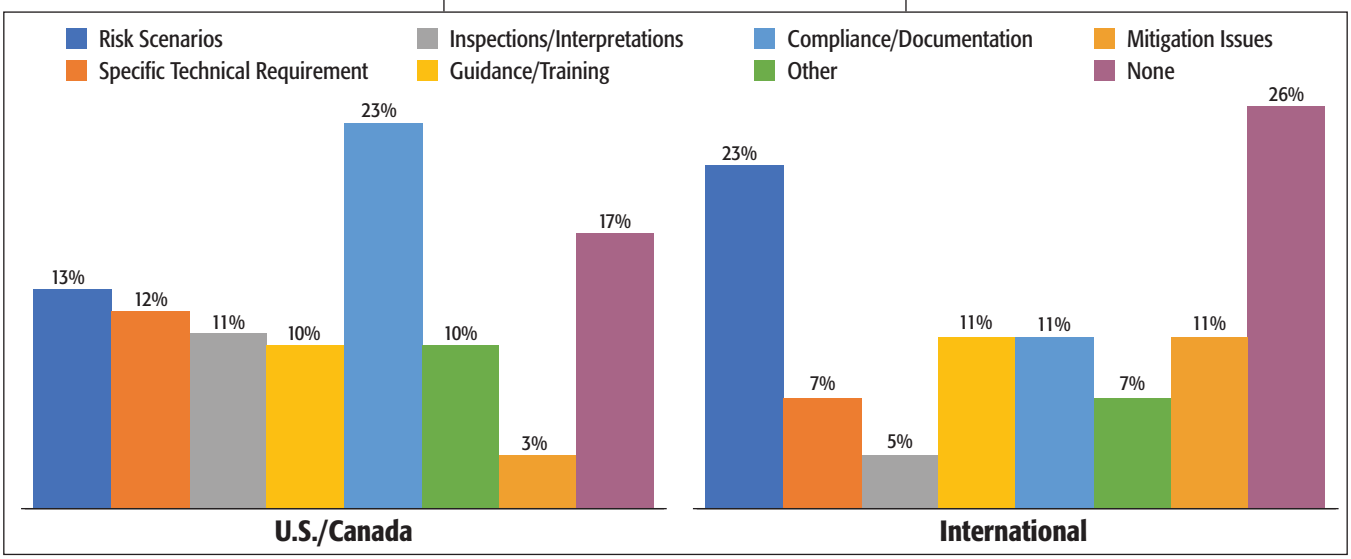

Figure 2. What are your biggest concerns with compliance with the FSMA IA rule?

the most opportunity to create an incident. Many processors especially highlighted their concerns over the presence of temporary workers. One processor commented, "With 500 hands handling the product, how can you watch all of them?" Most of the respondents to our survey felt the most likely risks were manageable, but that there were many more possibilities and scenarios than they could reasonably address.

It is these numerous but unlikely scenarios that seem to most vex processors. Many commented that it is easy to think of more possibilities than they could ever address. One processor mentioned that "we are trying to 'think like a criminal' to ensure we are considering all of the risks involved…" But how far do processors need to go? How many unlikely scenarios do they need to consider and how improbable does a scenario have to be until it no longer needs to be considered in their IA program? Or, as one processor described the situation, "Do we need to consider every crazy Ph.D. MacGyver-type scheme… or mainly keep the focus on the more likely possibilities from people bent on creating trouble?"

And confirming what we mentioned earlier about some processors perhaps being overly optimistic about their compliance readiness, 17 percent of the U.S. and Canadian processors and 26 percent of the international processors indicated that they have no concerns about compliance with the IA rule. While the possibility that nearly one in five processors has been able to create and implement a compliant IA program with no issues at all is encouraging, the comments that we have received from others on the IA rule, as well as on other issues related to FSMA from previous surveys, indicate that compliance issues are always highly complex and initially present many unanswered questions. Being able to get this right well ahead of compliance and inspection dates with limited guidance may be optimistic. But once the formal inspections start in March 2020, we'll find out for sure.

In the next issue of Food Safety Insights, we will address issues related to another type of intentional food adulteration, food fraud–or as known officially–economically motivated adulteration. We have all seen the reports and incidents related to unscrupulous actors misrepresenting one species of fish as another, substituting horse meat for beef, and diluting and coloring various oils to sell as high-quality virgin olive oil–all for the purpose of illegally making money. We wanted to find out more about food processors' experiences with these threats and what they are doing to protect their products, their markets, and their profits. Look for that report in October. ■

***Bob Ferguson** is president of Strategic Consulting Inc. and can be reached at insights@foodsafetymagazine.com or on Twitter at @SCI_Ferguson.*

By Patricia Faison

The Juice Industry's Commitment to Food Safety

Q&A with Patricia Faison of the Juice Products Association

What is your role in the juice industry?

I serve as the technical director for the Juice Products Association (JPA), the trade association representing the fruit and juice products industry. JPA's membership includes processors, packers, extractors, brokers, and marketers of fruit or vegetable juices, drinks, or bases, as well as industry suppliers and food testing laboratories. Our manufacturers represent over 80 percent of the U.S. volume of juice and fruit beverage production, plus companies in Mexico, China, and Latin America.

Why are food safety regulations important for the juice industry?

As with any natural fruit and vegetable product, there are health risks if juice is not processed, packaged, and transported safely. Juice must be pasteurized or otherwise treated to destroy any harmful bacteria. In the past, there were reports of outbreaks of foodborne illnesses traced to drinking juices that had not been treated to kill harmful bacteria. This led to the implementation of regulations such as Juice Hazard Analysis and Critical Control Points (HACCP) to ensure safety in juice products. Today, the juice industry is one of the most closely regulated industries for food safety.

What is the process for making juice?

The process involves three basic steps. First, the fruits or vegetables are washed carefully. Then, the juice is extracted by pressing the produce. Finally, the juice is typically heat-pasteurized for food safety. This process involves the application of heat to eradicate any contaminating bacteria. Some juices are alternatively made using high pressure processing or HPP. This is a cold pasteurization technique, where sealed and packaged products are subjected to a high level of isostatic pressure. This process helps eliminate a variety of pathogens in food and can help extend shelf life.

Could you describe the safety measures to which the juice industry adheres?

From the farm to your refrigerator, safety is the top priority for juice companies. All juices sold in the U.S., regardless of the country of origin, must adhere to the same strict safety regulations. Juice safety measures include:

HACCP

The juice industry is one of three industries overseen by the U.S. Food and Drug Administration (FDA)'s HACCP regulations. The seafood and dairy industries are also regulated under HACCP. Juice HACCP was put into effect in 2002. All juice-processing facilities must comply with HACCP, and such facilities are regularly inspected by federal and state agencies. In addition, juice imported into the U.S. for consumption must be processed to comply with the Juice HACCP regulation or be imported from a country with a Memorandum of Understanding with the United States that covers juice.

HACCP is a key FDA-regulated safety measure for the production of juice, addressing "the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling to manufacturing, distribution, and consumption of the finished product."

Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) promotes a proactive and preventive approach to ensuring food safety, outlining clear and specific

actions that must be taken throughout the supply chain to prevent foodborne illnesses and contamination. FSMA was enacted in response to dramatic changes in the global food system and a greater understanding of foodborne illness as both a public health problem and an economic threat.

FDA has finalized seven major rules to implement FSMA. These include the accreditation of third-party certification bodies to conduct food safety audits, the performance of risk-based activities to verify that food imports meet U.S. safety standards, and the establishment of science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables. Since FDA has previously established preventive control-type regulations for juices based on HACCP, the agency has exempted juice from several of the FSMA provisions. Juice processors comply with other FSMA regulations, as required, to ensure that their products are safe for consumption.

> "From the growers' farm to your refrigerator, safety is the top priority for companies in the juice industry."

Total Diet Study

To further ensure the safety of food and beverages, FDA also monitors levels of about 800 contaminants and nutrients in the average American diet as part of its Total Diet Study. Due to shifting eating patterns over time, the list of tested foods is updated about every 10 years. The study involves buying, preparing, and analyzing about 280 foods and beverages from areas across the country, four times a year.

These findings are then used to identify dietary trends, suggest potential areas of focus for FDA's food safety and nutrition programs, and guide the development of interventions to minimize risks when necessary. In addition to abiding by FDA's regulations, juice producers also conduct routine testing of their own to ensure quality control and safety of their products.

Pesticide Regulation

Pesticides are widely used to control pests such as insects, weeds, and plant diseases on many crops. The U.S. Environmental Protection Agency (EPA) sets tolerances for pesticide levels in food based on scientific risk assessments for consumers of all ages. These tolerances reflect EPA's determination that a pesticide can be used with "reasonable certainty of no harm."

EPA continuously evaluates new and existing pesticides and works to improve the safety standards related to pesticide residues on food. Juice companies are compliant with all EPA guidelines. As an additional preventive measure, juice producers source their produce from farms that comply with safe pesticide use. Fruits and vegetables are also thoroughly washed as the first step in creating juice.

The United States Department of *(continued on page 56)*

What the Next Generation of ATP and Food Safety Monitoring Looks Like

Food safety professionals must make sure that every step of their process is free of contamination and efficiently carries out safety functions like pasteurization and complete cooking. Today's professionals face significant challenges: complex supply chains, increased audit and inspection scrutiny, and the ever-present risk of contamination and recall.

According to the U.S. Centers for Disease Control and Prevention, one in six Americans becomes sick from eating contaminated food every year. Three thousand Americans die each year from food contamination, and it's estimated that such illnesses cost more than $15 billion annually.mic

Many methods can help detect and remove the threat of foodborne infection, ranging from visual inspections and record-keeping to whole-genome sequencing and chemical disinfection. But one method—detecting adenosine triphosphate (ATP), the source of energy in all living cells—has been proven to be a simple, cost-effective, and rapid first line of defense in food safety monitoring and hazard detection.

Previous studies have shown that food safety professionals using ATP are searching for—in order of importance—faster time to results, accurate readings, reproducibility, simplicity of use, lower costs per test, and reliable equipment.

Earlier this year, Hygiena introduced its new EnSURE™ Touch Monitoring System. The EnSURE Touch is a next-generation system that collects, analyzes, and reports data from multiple quality tests detecting ATP, microorganisms, and enzymes, providing necessary data for audit and risk management.

The EnSURE Touch features the superior chemistry, sensitivity, and reliability enjoyed by Hygiena customers and incorporates innovative design and functionality upgrades, including:

- A redesigned user interface that functions like a smartphone and can be configured to fit any facility or network of facilities. This introduces more flexibility than any existing ATP monitoring system.
- Wi-Fi capabilities and wireless sync technology for secure data transfer to new cloud-based analytics software.
- Collection and storage of important testing data, such as sample location, line name, cleaner used, and more.
- Training for remote teams with built-in screen sharing technology. ATP detection has been shown to be a valuable tool for education of staff and a powerful way to reinforce your facility's cleanliness and food safety culture.
- Responsive 5-inch, shatter-proof touchscreen that works while wearing gloves. This ruggedness expands the range in which the EnSURE Touch can be used.

The EnSURE Touch is designed with its users in mind. Incorporating key design features and options, it can be easily customized for industries like food and beverage manufacturing, foodservice, restaurants, hospitality, and more. The EnSURE Touch is accompanied by the latest version of Hygiena's SureTrend Data Analysis Software, SureTrend Cloud, which enables users to monitor, track, and trend testing results across one or multiple facilities, schedule automatic reports, and easily configure one or hundreds of monitoring systems from a single SureTrend Cloud account.

This software comes preset with reports, graphs, and charts that help management make cleaning improvements, train personnel, and clearly illustrate performance. Once testing has begun, results can be immediately analyzed to give feedback on cleaning performance and areas for improvement.

Just as important are the devices used to collect samples. These must be convenient to use, have a low risk of cross-contamination, and be effective. The EnSURE Touch uses the same UltraSnap™ and SuperSnap™ sampling devices used with previous instruments. These devices are all-in-one and ready-to-use, and contain a novel liquid-stable reagent formulation. These sampling devices are available for both solid surfaces (UltraSnap) and liquid samples (AquaSnap). All sampling devices have a simple snap-and-squeeze activation step, 12-month shelf life, and tolerance to ambient temperature abuse. The devices are slim and lightweight, thus combining ease-of-use with reduced environmental impact because they contain fewer parts and are 50–60 percent lighter than comparable products.

The EnSURE Touch will be able to test for specific microbes using MicroSnap™ indicator organism tests, as well as enzymatic tests like ZymoSnap ALP, which measures alkaline phosphatase activity to determine pasteurization efficiency, and CrossCheck ACP, which measures acid phosphatase activity to check for complete cooking.

Today's food safety professional needs fast results that can be measured accurately using technology that is flexible, versatile, and easy to use. Based on years of experience and proven technology, the new EnSURE Touch introduces a new generation of food safety testing that can identify anything from cleaning effectiveness to specific microorganisms.

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EnSURE™ Touch ATP monitoring system collects, analyzes and reports data from multiple quality tests including; ATP, microorganisms, allergens and enzymes.

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Present-Day Food Safety Leadership Advice for Future Food Safety Leaders

By Gina R. (Nicholson) Kramer, RS/REHS

I was 4 weeks into my new position as senior food safety & quality manager with The Kroger Co., Columbus Division, having lunch with my new boss. He wanted to know how I was transitioning from my former role in government. To be honest, I missed my colleagues and the team that I had supervised for many years. They were the most innovative, hardworking, and passionate team members that I was blessed to lead. They would move mountains to protect public health. They were full of integrity and loyalty to each other and me. I explained my feelings to Brad. Kroger was a huge company that ran like a well-oiled machine, but being responsible for food safety in over 350 stores seemed a daunting task for one person, me, to accomplish without a team. He smiled at my remarks and said, "Gina, I understand your concerns. Food safety is a BIG responsibility for one person. But a great leader is not determined by the number of direct reports that they supervise; a great leader is someone who can inspire and motivate an entire company to change. I believe *you* are that type of leader, not just for the Columbus Division but for the entire enterprise." Then we strategized on how to inspire and motivate thousands of associates to create long-term,

habit-forming food safety behavior change.

Little did I know that I would later be pitching for budgeted money needed to fund a food safety culture program to the president and CEO of the entire Kroger company (I still had no direct reports but an incredible team of colleagues). The result was a budget 10 times more than what I asked for because leadership believed it was so important that it needed to be fully funded for success: buy-in from the top through investment in food safety. "Inspire and motivate an entire company to change." I will never forget that lunch conversation. Brad was an amazing leader, and his words of wisdom had a profound impact on my life both personally and professionally.

According to the Gerald R. Ford Presidential Library & Museum, "Leadership is defined as 'a process by which a person influences others to accomplish an objective and directs the organization in a way that makes it more coherent and cohesive.' A good leader is one who is always three steps ahead of the others. He looks out for the people before himself." I have found that this is the best definition of leadership as it is what I have experienced from my leaders and mentors over the years that has made a positive impression on my life.

The human ego is an interesting portion of self-belief that at times exhibits humility and other times explodes with pride. It is an internal struggle that every human battles. Ego becomes an interesting element when discussing leadership. Mistakenly, title, position, level of education, and salary are often used to define when someone has arrived at the ultimate leadership position. This is found in every profession and industry, even in food safety. I have to admit that I struggle with ego battles daily. The battle always ends in the triumph of servanthood in protecting public health because that is what a career in food safety is—servanthood.

There is no doubt in my mind that food safety has some of the best leaders. Numerous books and articles have been written on food safety management and developing a food safety culture by those many have called "food safety rock stars." During my 20-plus years in food safety, I have had the opportunity to work with many great leaders, learning from them, asking about their journey, their successes, and their failures. How did they become a leader? What influenced them? How were they able to build a robust food safety program? What words of wisdom would they like to share with undergraduate and graduate students looking at a career in food safety? This article contains bits and pieces of conversations and words of wisdom from those who have influenced many people, especially me. Those who may not have written books or published lots of articles but have dedicated their careers to the "servanthood" of public health and have become successful veteran food safety leaders.

Becoming a Food Safety Leader

Most food safety leaders today did not begin their careers as leaders. They began as a local public health inspector, analytical lab technician, healthcare professional, research assistant, restaurant manager, culinary chef, administrative assistant, and so on. They all started with entry-level positions and worked their way to leadership. One thing that I found they all have in common is a passion for food safety and protecting the consumer's health (see "The Importance of Leadership in Food Safety," p. 32).

As I spoke with Ann Marie McNamara, who has had a diverse career with government, laboratories, manufacturing, quick-service restaurants, grocery, and distribution, about becoming a food safety leader, she emphasized the importance of learning the science and developing the technical skills. It is essential that food safety leaders have a knowledge of the science of food safety. "They have learned to be proactive, good at risk assessment and developing strong preventive programs. They also need to understand HACCP [Hazard Analysis and Critical Control Points], preventive controls, recall programs, etc." She went on to stress that these are not the only skills, but they do provide a solid foundation.

Courtney Halbrook with Top Golf shares that becoming a food safety leader is a constant state of learning. She says, "You have to know your stuff, science, technical, regulatory, etc. Don't discount the experience you should get in the field in operations. Those that you lead and counsel will need to know that you have worked shoulder to shoulder with them. You understand and have worked in operations. This is what will allow for your success." Have you worked in the store or at the processing facility side by side with frontline food employees?

"The best training I received when I started in the food safety/quality assurance (FSQA) department at Wendy's was working in a store for 1 full month learning how to take customer orders, making french fries, cooking burgers on the grill, and opening and closing procedures. This allowed me to understand how to implement practical application of food safety at the store level because I understood their job," explains Barb Hunt, former Wendy's QA manager. Many food companies require that all corporate employees spend time working in the processing facility, distribution center, or at the store each year so they have firsthand knowledge of operations as they develop new products or programs that require changes to policies and procedures.

Learning Soft Skills

The most successful and influential food safety leaders do not rely on their technical and operational (hard) skills to inspire and motivate a company toward food safety change. They learn soft skills. According to zety.com, hard skills are teachable and measurable abilities such as writing, reading, math, or ability to use computer programs. By contrast, soft skills are the traits that make someone a good employee, such as etiquette, communication and listening, getting along with other people. Soft skills are personal attributes that enable someone to interact effectively and harmoniously with other people. "Scientists are so involved in data that they have a tough time in speaking with emotional intelligence to other business partners," states Ann Marie. She suggests food safety professionals read the book *Emotional Intelligence 2.0* and take courses on emotional intelligence.

Communication is the key in developing soft skills. Learning how to make eye contact when speaking; getting to know your colleagues on a personal level; being aware of your body language and others' body language; practicing both formal and conversational

speaking; and developing writing skills that focus on translating technical information into simple, understandable language levels that nonscientists would understand.

Other soft skills to develop are building relationships within your organization. This allows you to build trust, integrity, and respect among your peers and leaders. "Learning how to adapt and be flexible is a key competency. Utilizing cross-functional teams and learning how their role impacts the business," shares Sharon Wood with HEB. "Becoming a food safety leader is a journey and requires more than an academic résumé and knowledge. It requires that you learn how to speak to others' listening." Learning how others receive and interpret information is an important skill of an influential leader.

Acquiring Business Acumen

My very first day on the job with Kroger, I attended the Monday morning sales meeting. Each district reported sales of the past week, talking about same-store sales and then moving to discussions on division performance, earnings before interest, taxes and amortization, and profit and loss for the week. Presentations were forecasting revenue for the weeks ahead as merchandisers introduced sale items in their specific departments. This was all a foreign language to me, and I really had no idea what they were saying. I was expected to attend this meeting every week, so I knew I needed to learn this new language. I had to learn "Kroger Speak," or business acumen, to understand the business. I was the only one in the room of 40-plus people who did not speak this language. To make an impact on food safety, I needed to learn how to communicate to my new colleagues in their language.

Food safety professionals are known for coaching, teaching, and training others about proper food safety terms and practices. Sometimes we get so wrapped up in teaching others that we forget to stop and learn the business language within our own company. To inspire, motivate, and lead a company to change in food safety, we need to learn how to communicate our messages effectively. Chirag Bhatt emphasizes the importance for food safety professionals to interact with as many people as possible in as many departments as possible because it takes everyone within a business to be responsible for food safety. Don't be shy. You need to be your own advocate.

"It is important for food safety leaders to realize they are also a business partner to the company. Use business-speak. Learn company budgeting, marketing, mission, and strategy of business," Ann Marie emphatically advises. "Learn how to appropriately speak to the C-suite. Boil technical information down into understandable talk-

ing points that nonscientists will understand. Don't get lost in the details."

Learning how to calculate the daily value of food safety in dollars and cents is a valuable tool. Know where food safety adds value to the company's bottom line. Food safety leaders need to learn how to calculate the cost of food safety success and the total cost of food safety failures (recalls, customer complaints, foodborne illness outbreaks, etc.). Following proper food safety practices can show a savings in labor, utilities, supplies, and workplace safety; improve food quality and product shelf life, and extend equipment performance; and impact sales and revenue. All of these areas can be calculated to show daily value added to the business.

James Ball with Fresh Market states that, "Food safety conversations need to happen with executive leadership on a regular basis. Having a conversation in front of upper and middle management is very important." You must understand how to have these conversations in their business language to be able to move the needle forward on food safety. Terry Levee with Giant Eagle provides simple talking points to his CEO because she starts every morning talk about safety (food safety and workplace safety).

I spoke on this topic several years ago at a conference; during the Q&A period, one of the attendees asked, "So I guess I need to drink the Kool-Aid in order to do my job?", implying that if the food safety team learned the business acumen and began acting as a business partner that they were "giving in" to the business culture. But commitment to food safety matters at all levels of the company—especially the upper levels.

"For food safety leaders to motivate and enact change, it starts at the top and moves down. Promoting change from business partners means that food safety leaders must know their business partners' role within the company and how they might support change," shares Ann Marie.

A food safety leader cannot influence a positive culture of food safety without becoming a business partner. It is as simple as that.

Building a Food Safety Organizational Structure

I am often asked, "What is the best organizational structure for food safety?" My reply is always a question: "What is your business's organizational structure and culture?" You see, there is no silver bullet. A company cannot structure itself into food safety compliance or culture. The structure needs to fit the business. I have seen food safety report to marketing, legal, risk management, fiscal, R&D, operations, and even the CEO. "In my experience," says Ann Marie, "the structure that is right will depend on the culture of the organization."

Organizational structures are fluid, not static, which means they are always changing to better serve the business. What worked 2 years ago may not work this year. Structures change according to business strategies and needs. Food safety leaders need to be adaptable and flexible when structuring team members for their program. The business may require that staff work remotely one year and then change to centralizing all essential personnel to corporate headquarters the next year.

I always recommend looking at other business units' structure, titles, and job descriptions when building a food safety department from scratch or making robust changes. Find examples of successful structures and not so successful ones within your company. Network and ask how, when, and for what reasons a business unit is structured a particular way.

"Partnering with different business unit teams is important when needing to add essential personnel to food safe-

The Importance of Leadership in Food Safety

When you're hungry, you always expect to eat food that is safe and of high quality. Sometimes food processors don't deliver quality foods, but under no circumstance should they deliver a food that is not safe. Because a lot can go wrong when growing or manufacturing food products, food safety has become an extremely complex discipline and requires years of knowledge and experience. Coming up with a food safety plan and culture for an organization doesn't simply occur overnight.[1] The development of a food safety culture requires leadership. For a business to become an outstanding leader in food safety, it must have a culture dedicated to food safety, a leadership structure with a great foundation, and people who have the personalities associated with being an excellent leader.

The concept of food safety being understood and executed by a business must be instilled in the organization's culture, a combination of values and beliefs shared by its people, both inside and outside the organization, that informs the decisions made at every level.[2] Having such a culture is critical to a company that makes food products because it provides a sense of shared purpose among all individuals and contributes positively to the business.[2] Without it, the company is at risk for unsafe food and costly consequences.

Developing culture involves many steps. First, a food safety culture must filter down from the company's top leaders and executives to the plant floor. A second step is having management set a good example by demonstrating to other employees the correct way of doing something.[3] A third critical step is holding people accountable for adhering to food safety rules. In addition, employees must be proactive and prevent food safety incidents before they occur.[3] A fourth step is giving enough training in food safety to everyone working in the organization, whether or not they directly handle the food. These concepts are all part of Good Manufacturing Practices, and

ty," states Sharon Wood. Leaders must prove why they need additional resources and answer these questions: What is the standard of work? How do you measure the work of a full-time employee? Leaders will need to show the metrics and have solid estimates based on numbers. Partnering with planning, fiscal analysts, continuous improvement, and other business units is a must.

There may be times when outsourcing different job duties on your team makes for a stronger structure and budget. Robert Maldonado from Northgate Markets has found that building strategic partnerships with consultants, third-party auditors, technology providers, and chemical sanitation companies as an extension to his team gives him confidence in providing food safety support to all areas of the business.

Another valuable tool is to ask food safety colleagues to share their food safety structures (as long as it does not pose a conflict of interest or risk sharing confidential information). Trade organizations also provide valuable information in this area. Never be afraid to ask.

With Power Comes Responsibility

Most business colleagues are intimidated by science, especially food safety. This intimidation can cause fear of roadblocks to innovation and product development, which results in excluding food safety from participating on these teams at inception. "With new projects, products, and concepts, the FSQA person needs to be brought in early with the company. The objective of a food safety leader is not to say no but to say, 'Let me go back and research alternatives that will help move the project forward," advises Ann Marie.

I think every food safety professional has heard an idea or an innovative solution to a business problem and immediately began to think about all the problems. "Be open to new ideas! It is better to say "how" rather than "no" as long as public health is not compromised," says Sharon. A quick "no" without justification can cause innovation to occur in a vacuum, without food safety being involved, which can be detrimental long term to protecting the brand, the consumer, and business success.

Food safety professionals are looked upon as subject-matter experts and advisers to business leaders in regulatory compliance, brand protection, accountability, key performance indicators, and public health. Ann Marie remarks that effective food safety leaders must develop courage: "Courage to stand up and do what is right."

Words of Wisdom for Future Food Safety Leaders

As my recent conversations with experienced food safety leaders about this topic came to a close, I asked each one to give me in three to four sentences words of wisdom that they would like to share with future food safety leaders. Below are "nuggets" that new college graduates could take with them as they begin their careers in food safety.

"Gain experience in as many areas as possible: government, manufacturing, retail, service providers." – Robert Maldonado

"Understand the basics that need to be in place. Add simple tools. Measure performance and react to metrics. Benchmark against other companies. Explore how to push forward within the boundaries of your company's budget restraints." – James Ball

"Food safety has to be built on a level of trust with other business units. Otherwise, it is only seen as the police and not a business partner." – Courtney Halbrook

"Conduct gap analysis and benchmark with other companies. Strive to be best in class." – Terry Levee *(continued on page 54)*

production employees should know and understand each and every one of them to grasp the "why" behind what they are doing.[3] Reinforcing the food safety message draws an emotional link so that food manufacturers are more cognizant of a food's safety and quality. Finally, it is important to focus on changing behavior of employees so they think proactively about food safety.

Only after employing these concepts can the food safety leadership structure begin to take shape. An excellent food safety leadership structure starts with every individual clearly understanding his or her role and responsibility.[4] This enables clear handoffs between other employees who work in different parts of the process. Implementing a food safety structure raises a lot of questions: How is the leadership structured? Which department is responsible for a particular step? Is there another department that the job can be delegated to in case of bottlenecks? Who will actually do the work?[4] The final question to ask is, Who is ultimately accountable or really responsible for making it happen?

A food safety leadership structure first needs food safety leaders. In fact, food safety leaders are needed now more than ever due to the constantly changing nature of food and food safety.[5] Which personality traits make an awesome leader depends on whom you ask: Some people say that leaders are born with the personality of a leader rather than taught to have the leadership mindset, but most agree that seven important characteristics of a fabulous leader are "zest, grit, optimism, self-control, gratitude, social intelligence, and curiosity."[5]

– Megan Doran, B.Sc.

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By *Food Safety Magazine*

Keeping Food Safe in the C-Store Environment

The evolution of food safety at convenience stores

"Gas station sushi": Most of us have heard someone use this term to summarize food offered at convenience stores (C-stores). The saying evokes thoughts of a cheaply priced, half-rotted, foul-smelling, and unsanitary product that will make a consumer immediately ill upon ingestion. However, modern C-store foodservice programs have shattered the notion of "gas station sushi" by focusing on providing consumers with high-quality offerings produced and served in a clean and sanitary environment. Today, a consumer can expect to find everything from fresh-cut produce to handmade premium sandwiches and artisanal coffee at their local C-store. In the *2019 State of the Industry* report, the National Association of Convenience Stores noted that foodservice sales accounted for the second-largest contributor to in-store sales (22.6% as compared with leader tobacco, which accounted for 31%). Capitalizing on these statistics, C-stores have made the development of foodservice programs a key focus to drive in-store traffic and distinguish themselves in the competitive C-store market. For these programs to continue to be successful, the need for strong food safety systems and policies aimed at consumer and brand protection has become more important than ever. However, due to the relative newness of premium foodservice offerings, C-store food safety professionals struggle to find food safety-related resources aligned with the complex challenges unique to the C-store environment.

Given the great importance and contributions of C-stores in the food industry, *Food Safety Magazine* convened an expert panel, moderated by Jeremy Zenlea, director of food safety, Cumberland Farms, to address some of the more critical questions regarding the challenges surrounding the C-store food safety culture. Participating panelists were Charles McGuffey, retired head of global food safety and quality assurance at 7-Eleven Inc., International Division; Jay L. E. Ellingson, Ph.D., senior director of food protection and science opera-

tions, and Marty Putz, director of food protection – retail, Kwik Trip; Richard Sterling, director of food safety North America, Circle K Stores; Chirag Bhatt, food safety professional; and Steven Mandernach, J.D., executive director at the Association of Food and Drug Officials (AFDO).

Food Safety Magazine: How does the variety of food products sold in convenience stores complicate the creation of food safety management systems or policies within the establishment?

Charles McGuffey: A variety of products is not as much a problem as one might think. Minimizing basic risk factors (cross-contamination, time and temperature control, employee hygiene, and shelf life) after the items are delivered to the stores is critical and most challenging, however. Staff training and consistent/perpetual monitoring are critical in this high-employee-turnover industry and must be kept as simple as possible and practical. Minimizing in-store preparation and staff handling is key when developing products. The process must begin with the suppliers and continue through the delivery system. Working with suppliers to develop category- and product-specific equipment with automated fail-safe equipment and short shelf life for fresh products and ingredients for in-store prep items is key to minimizing risks and optimizing quality.

Staff training and consistent/perpetual monitoring are critical in this high-employee-turnover industry and must be kept as simple as possible and practical.

–Charles McGuffey

Jay L. E. Ellingson and Marty Putz: With the creation of a food safety management system, companies need to break the variety of food products into different categories. The obvious categories are refrigerated, frozen, and shelf stable, but within each of those categories there can be concerns. A C-store that has minimal food offerings, using pre-packaged products with a limited variety, does not have the same requirements for a food safety management system. Most food is reheated, maybe even by the customer themselves. The hot-holding and preparation is minimal. On the other side of the spectrum, a C-store that prepares a large variety of products needs to create a more robust food safety management system. Increases in food handling or custom-made orders can challenge food safety. Traditionally, C-stores are challenged with kitchen space and design; if the store has a smaller footprint, it can be a challenge for adequate prep or storage space. Segregating raw and ready-to-eat products throughout the store (storage and prep) and the introduction of process controls in small spaces are very challenging.

A C-store that has minimal food offerings, using pre-packaged products with a limited variety, does not have the same requirements for a food safety management system.

–Marty Putz

Jeremy Zenlea: Unlike in manufacturing, quick-serve or full-serve restaurants primarily focus on offering a specific line of products to a uniquely targeted consumer demographic. In contrast, a C-store focuses on targeting all consumer demographics by offering a wide variety of food and beverage options to be presented in multiple formats. Take bakery items, for example: C-stores offer bakery items in several different formats—grab and go (from a bakery case), heat and serve, or in a retail package. Each of these delivery methods for the same item means that we have to design and implement several different Standard Operating Procedures to cover that one type of product. Now multiply that by all of the other product types offered in a variety of formats, adding in limited food prep and storage space, and one can easily understand how complex the food safety management system at C-stores truly is.

Richard Sterling: The busy lifestyles of today's consumers have driven them to demand the on-the-go convenience of snack and grab-and-go foods in place of meals, and they now look to C-stores as food destinations. Many C-stores have already transitioned over to food as a destination driver, and their offerings include a variety of fresh foods such as sandwiches, wraps, salads, and cut fruit, as well as ethnic, vegetarian, and gluten-free foods.

In addition to consumer demand for variety, there is also the expectation of quality and "freshness" from the C-store food offerings, typically manifested by the inclusion of produce and nontraditional ingredients and components in prepared foods.

The increasing amount and variety of food products prepared and served in C-stores, along with the food safety risks posed by many of these relatively high-risk items (such as produce), requires that C-stores work collaboratively with—and place more accountability on—suppliers, broad-line distributors, and other supply chain participants to mitigate these food safety risks.

Although many provisions of FSMA [the Food Safety Modernization Act] do not apply to C-stores/foodservice, this legislation has put renewed pressure on C-store operators to fully implement preventive controls (such as consistent and reliable temperature monitoring for equipment and food) rather than relying on reactive processes after failures occur.

On the other side of the spectrum, a C-store that prepares a large variety of products needs to create a more robust food safety management system.

–Jay L. E. Ellingson

Chirag Bhatt: Having several areas where food handling occurs, active managerial control to manage the most common risk factors is very important. Suppliers and their food safety, proper holding temps, and personal hygiene (including adequate handwashing) are key factors. Critical Control Points must be addressed efficiently.

Steven Mandernach: Convenience stores have changed greatly in the last two decades from primarily pre-packaged foods, with a soda fountain and maybe a hot dog roller, to a full menu of foodservice products, coffee bars, and more. The greater the number of temperature-controlled-for-safety (TCS) items that are sold and prepared in the facility, the more likely it is for it to have issues with food safety. The product mix will determine the food safety controls necessary, and different types of items means different controls to handle. Some chains expanded their product lines, but they did not always recognize the increased need for food safety professionals and training, which resulted in challenges. More prepared products increase the amount of time to prepare the items and the amount of training time necessary. The large number of products the employee is trying to prepare and maintain can be overwhelming. This can lead to poor practices such as not taking temps and poor handwashing.

As chains consider expanding product lines, visiting with the regulatory agencies in the states in which they do business can help identify potential challenges in advance and avoid regulatory challenges in the field. More prepared products require a greater amount

of employee training in food safety, which can be challenging to achieve in the C-store environment.

Further, the independent or small chains, in their effort to compete with the larger chains, are often making the expansions into prepared foods without the food safety knowledge, written policies, and infrastructure to support the expansion.

FSM: What resources are available to convenience stores in terms of food safety? Do you have to adapt what is available for other segments of the food industry or create your own?

CM: Utilizing basic food safety best practices, we developed our own category and product-specific procedures for sourcing, delivery, receiving, storing, prepping/handling, serving, and monitoring all products with a shelf life. Combining the expertise of our category management teams and food safety quality assurance team with our store training and development team, we created both hands-on and CBT (computer-based training) resources for new and ongoing store staff training. All training materials are easily accessed on our in-store computers from headquarters to every store for easy reference and follow-up "just in time" instructions as needed. (All company employees from management to store staff are required to complete initial and follow-up training.) Store cleanliness and staff health/hygiene procedures are developed and trained with a goal of "the easiest way being the right way"…more likely to be executed in the fast-paced, high-volume environment. For fresh food items, both "category" and "product-specific" procedures are a must. Standardized equipment, tools, supplies, recipes, and ingredients are critical in order to globalize consistency in quality and quantity.

Unlike in manufacturing, quick-serve or full-serve restaurants primarily focus on offering a specific line of products to a uniquely targeted consumer demographic.

–Jeremy Zenlea

JE/MP: There are not that many C-store industry-specific food safety references out there. Convenience stores must reference full-service or quick-service restaurants' best practices; some C-stores are bridging the gap (producing their own resources)

due to the variety and customization of food and beverage items previously mentioned. We utilize the ServSafe programs and materials. With ServSafe, you'll get materials developed by foodservice industry leaders and supported by the National Restaurant Association. ServSafe training helps you understand food safety risks faced by operations. Having said all that, ServSafe covers a variety of "raw" products assuming they will be cooked using a grill/fryer/oven; many of these products don't come in the raw state for convenience stores–again, not always a good resource for convenience stores. Sometimes, once again due to the smaller footprint, creativity can be necessary to ensure food safety in unique environments, creating a food safety management system to bridge the gap between food safety needs and business needs. Yes, we do have to adapt training materials (such as ServSafe) to fit the convenience store segment.

The busy lifestyles of today's consumers have driven them to demand the on-the-go convenience of snack and grab-and-go foods in place of meals...

–Richard Sterling

JZ: Foodservice operations and the need for robust food safety resources in the C-store industry is relatively new when compared to restaurants and food manufacturing. Therefore, most food safety-related resources and trade organizations are largely focused on and designed for those industries. This essentially means that there is no "book" or benchmark we can reference when implementing and designing a new program, so we are forced to get creative and actively work with vendors to customize their products or build a product from the ground up so that it works within the C-store space. These resources are more expensive than the out-of-the-box options, take longer to implement, and there is no guarantee that they will work as intended. This negatively impacts our ability to roll out new food programs in a timely and cost-effective manner as we will not introduce any new food items without a strong food safety program behind them.

RS: A major resource that has proven invaluable for food safety is my company's intranet. Recent enhancements and capabilities have enabled the quality and food safety group to post and track required food safety education and training campaigns to targeted individuals at all levels of the organization.

Also, digital tools have proven to be a more efficient and cost-effective solution for our internal food safety audit process as compared to the usual pen-and-paper method often used in C-stores and foodservice sectors. Coming from a food processing background, I'm naturally inclined to adapting processes from that sector to my present C-store role, especially since food processors had many of these same challenges years ago and found viable solutions through emerging technologies.

We are actively exploring newer technologies that enhance quality and reduce foodborne illness risks such as (1) blockchain and other integrated technologies to facilitate product traceability and supplier management, (2) remote monitoring to automate aspects of our equipment and product temperature compliance, and (3) Internet-of-things technologies to monitor water filtering and flow in dispensed beverage equipment. External resources such as third-party food safety audits are being deployed to ensure compliance to our food safety operational methods and practices.

CB: Your typical food safety management system is universal, and if the specific protocol works for a restaurant or supermarket, it will work in a C-store. After all, it is not rocket science, just food science.

SM: From a regulatory perspective, most of the guidance documents and handouts developed for other types of retail establishments apply directly to convenience stores also. Further, many convenience store chains have recognized the additional food safety challenges in their sector and have joined other professional associations to leverage the learnings of other sectors.

FSM: How challenging is it to manage the frequent deliveries of refrigerated products and other items with limited shelf life? How do you ensure cold chain management?

CM: We developed our own fresh food daily-delivered commissaries and warehousing/distribution centers and complex picking and sorting logistics systems to meet this challenge. Suppliers delivered to our distribution centers, then store-specific customized orders are handpicked or through automated picking, and then delivered in one delivery each day…always scheduled so the store is properly staffed and ready to receive every delivery utilizing the standardized food-safe procedures. Automated records always kept and filed as standard procedures. This process also frees up customer parking space that would be blocked by multiple delivery vehicles.

JE/MP: Depends on the number of deliveries a single store will receive and where these deliveries are received from. If you're shipping from a centralized warehouse that is part of your supply chain, there is much more control on the cold chain. If you're utilizing a third party to distribute to stores, then you must ensure the cold chain is managed. Companies that operate their own fleet of trucks/trailers and self-distribute can control the cold chain. Regular deliver-

ies of product can help maintain good shelf life/turns with these perishable products. In many cases, the cold and frozen sections of the trailers are monitored via fleet management systems. When delivered, products are moved quickly from the truck to the area they belong in order to maintain the cold chain (walk-in coolers or freezers). Any deviation from the above could mean temperature abuse with temp-sensitive products both refrigerated and frozen. Once delivered, it is the store's responsibility to label, maintain, and stock the items per existing programs.

JZ: Regardless of the type of food industry you work in, managing the cold chain is going to be a challenge. Temperature monitoring–whether by a remote sensor, TempTale, or a person–is key throughout the entirety of the supply chain, including at store level. The challenge lies in the fact that we have to manage frequent, small deliveries within a short amount of time to stores that also have limited storage space. Thus, the temperature-controlled environments within the trailers are continuously being disrupted and their contents are being staged in non-temperature-controlled areas while waiting to be put away. To best maintain the cold chain during these interruptions, we rely on our greatest asset to food safety–the store team members. Our team members are trained so that they understand basic food safety principles, such as proper temperature storage. Using these principles, they implement receiving procedures and storage methods that enable them to receive food quickly and efficiently. Store design also plays a major role in maintaining the cold chain; for instance, coolers and freezers are located in close proximity to the receiving door and designed to quickly cool down to safe temperatures once the receiving process is complete.

RS: Frequent food deliveries are a fact of life for convenience store foodservice, primarily due to the relatively short shelf life of the food products and limited storage space for TCS foods. Store employees are required to (1) inspect food deliveries for condition, (2) measure and document incoming refrigerated and frozen food temperatures to verify they are within the specified parameters, and (3) quickly store the food in refrigerators and freezers within a specified time. When stores are faced with the inevitable delivery of food during peak customer hours, it can become very challenging for store employees to handle their other tasks (cash register, food prep and service, etc.) while maintaining [the] cold chain of this incoming product.

Your typical food safety management system is universal, and if the specific protocol works for a restaurant or supermarket, it will work in a C-store.

–Chirag Bhatt

CB: To accommodate limited shelf life and limited storage space (in many cases), deliveries that are more frequent may be beneficial, and utilizing a reputable and food safety-compliant distribution company, this task can be managed.

SM: Many times, deliveries are occurring all day and they can sit unnoticed for long periods of time. Beer tends to go straight to the cooler and stocked by the drivers, but other items can be out of temperature control for extended periods. We are seeing more refrigerated products being delivered directly into the cooler, which limits the sitting of deliveries for long periods of time outside of refrigeration. The limited staffing to verify the temperatures of deliveries and ensure quick temperature control continues to be a challenge. When there is adequate staffing, there tends to be sufficient cold chain management.

FSM: What do you see as the outstanding needs for food professionals at convenience stores?

CM: Basic training and professional licensed certification, along with the dedicated staffing resources and commitment to "doing what is right" with or without supervision, is the greatest need for food professionals at convenience stores. Training resources are abundant.

JE/MP: For store teams: training and guidance! Today, companies have a number of options to address training: ServSafe, computer-based training, and hands-on training for all other coworkers. Constant coaching is needed to remind foodservice employees of what the expectations are and *why* they are necessary. Explaining the reasoning for food safety practices will often result in employee buy-in, and even peers keeping each other accountable in a respectful manner.

For corporate/management: true dedication and buy-in. When senior leadership and operations management understand the importance of food safety in developing food programs, you are already ahead of the curve. Having to work just to get resources, involvement, or consideration is an unnecessary obstacle that takes away from time that could be spent developing programs, researching/participating in share groups, and ultimately mitigating the same risk that could put an end to your food programs in a worst-case scenario.

JZ: C-store food professionals need more avenues to openly collaborate and share best practices. It is no secret that there is still a negative public perception of the quality and safety of food offered in C-stores. Because of this, consumers tend to equate any negative food-related experience they have with the industry as a whole rather than just the brand name of the store from where they bought the food item. This need can be satisfied if more of the existing food and convenience store trade organizations enact subgroups or committees focused on solving C-store-related food safety issues.

Many times, the staff have a high rate of turnover, and minimal investment is made to ensure they have the basic food safety knowledge needed for food workers.

–Steven Mandernach

Another need for C-store food professionals is a food safety system benchmark or standard that we can reference or strive for. The only standards that are available focus on other segments of the food industry and thus are hard to apply to C-store foodservice operations. Take the certified food protection manager, for example, as part of the FDA Food Code: We are required to have certified food protection managers on staff. While this is a great idea and will result in decreased consumer risk, the certification schemes made available by trade organizations are designed for full- or quick-serve restaurants and thus contain a lot of information that is not value-added or relevant for C-store personnel. Creating a benchmark will elevate the level of food safety for all C-stores, leading to fewer outbreaks, recalls, and any other negative consumer food-related experiences. This will inevitably help change the negative public perception of C-store food and drive more traffic into our stores.

RS: Rather than being characterized as transactional and reactive, the efforts of food safety professionals at convenience stores must encompass the following:

Training: Food safety professionals should be empowered to drive consistent, regular, and ongoing food safety education/training programs for all levels of the organization (including annual refreshers) in order to create a food safety awareness culture.

Internal assessments: After food safety training programs are implemented, food safety professionals should be provided with the responsibility to require accountability through internal and/or third-party assessments that will identify nonconformances and gaps.

Corrective actions: Sustainable corrective actions can then be developed through collaboration of cross-functional teams and departments, and deployed, resulting in continuous food safety improvements over time.

Processes codified: Written food safety processes and practices should be revised (at least annually) to reflect the improvements and best practices.

CB: For locations where adequate (and properly trained) staffing becomes an issue, food safety can be at risk as the team members may be multi-tasking, such as mopping the floor and turn around to make your pizza behind the counter. Let us keep our fingers crossed that the team member washed hands before getting that pizza in a box.

SM: Training continues to be a big challenge for C-store staff members. Many times, the staff have a high rate of turnover, and minimal investment is made to ensure they have the basic food safety knowledge needed for food workers. Further, staffing can be an ongoing challenge in this environment even more so than some of the other retail-type facilities. Staff are often repurposed to the most immediate challenge present. This can present a challenge in maintaining food safety by not having staff focused on this area.

Chains have often developed excellent procedures that if followed will maintain food safety but have not trained the staff members responsible for implementing these procedures adequately. They have a great system on paper, but it isn't put into practice.

We also see hepatitis A as an area for ongoing concern in the C-store industry, similar to all retail. C-stores need to be very conscious of hep A and the potential for transmission in a food environment.

FSM: What would you say is the most difficult aspect of your job?

CM: Bottom line: Keeping stores staffed with dedicated food handling professionals was most difficult. Developing/instilling the food safety mentality (sometimes referred to as "second nature") in every store staff member, compelling them to "do what's right," and exemplifying the same with colleagues is the greatest challenge and global goal–and praising/rewarding them for the same.

JE/MP: Trying to keep up with the pace that other company management moves at. New items, recipes, and processes are sometimes brainstormed, drafted, developed, and in place (with plenty of excitement surrounding them) before food safety has adequate time to assess the risk and develop a plan to handle it.

JZ: The most difficult–and exciting–aspect of my job is that in order to run an effective food safety system for a large C-store chain, one can never sit back

and rest on their laurels. They must always be constantly studying and learning about all of the things that directly or indirectly affect the food safety of our food offerings. This includes ensuring that you have an expert-level understanding of different state, town, and federal regulations, latest food safety trends, all parts of the supply chain (manufacturing, storage, transportation, retail, etc.), and all the risks associated with the different categories of food produced in the commissary and offered in-store. Like other retail industries, C-stores are constantly evolving and changing to meet the demands of the consumer. Thus, it is important that your food safety systems can meet the demands of the company without compromising food safety.

RS: One of the most challenging is supporting different business units across the U.S. in their efforts to comply with local regulatory requirements. Although the majority of state health departments have adopted FDA's Food Code (either the 2013 or current 2017), enforcement criteria of the various agencies can often be different among state and/or local health departments (e.g., a few states require that signage is posted in the C-store eating area, accessible to both employees and customers, detailing the steps to aid a choking victim). It is a rare week when I don't have to review and interpret a local code in an effort to support a group of affected stores within a state or region.

CB: Food safety professionals at a convenience store–like many others–will be faced with the constant turnover issue and having to retrain the new team members. Training and refresher training becomes challenging due to limited resources. Best advice–get them trained before they touch any food item and refresh it every 2 years. Daily reminders about important topics can go a long way.

SM: Getting the establishment employees to understand the importance of food safety when they can barely keep up with their immediate duties; when there's a line of customers waiting, the employees may not see taking a temperature or washing their hands to be a high priority. Periodically, chains operating in many jurisdictions may have policies or procedures that do not conform to an individual jurisdiction's regulations.

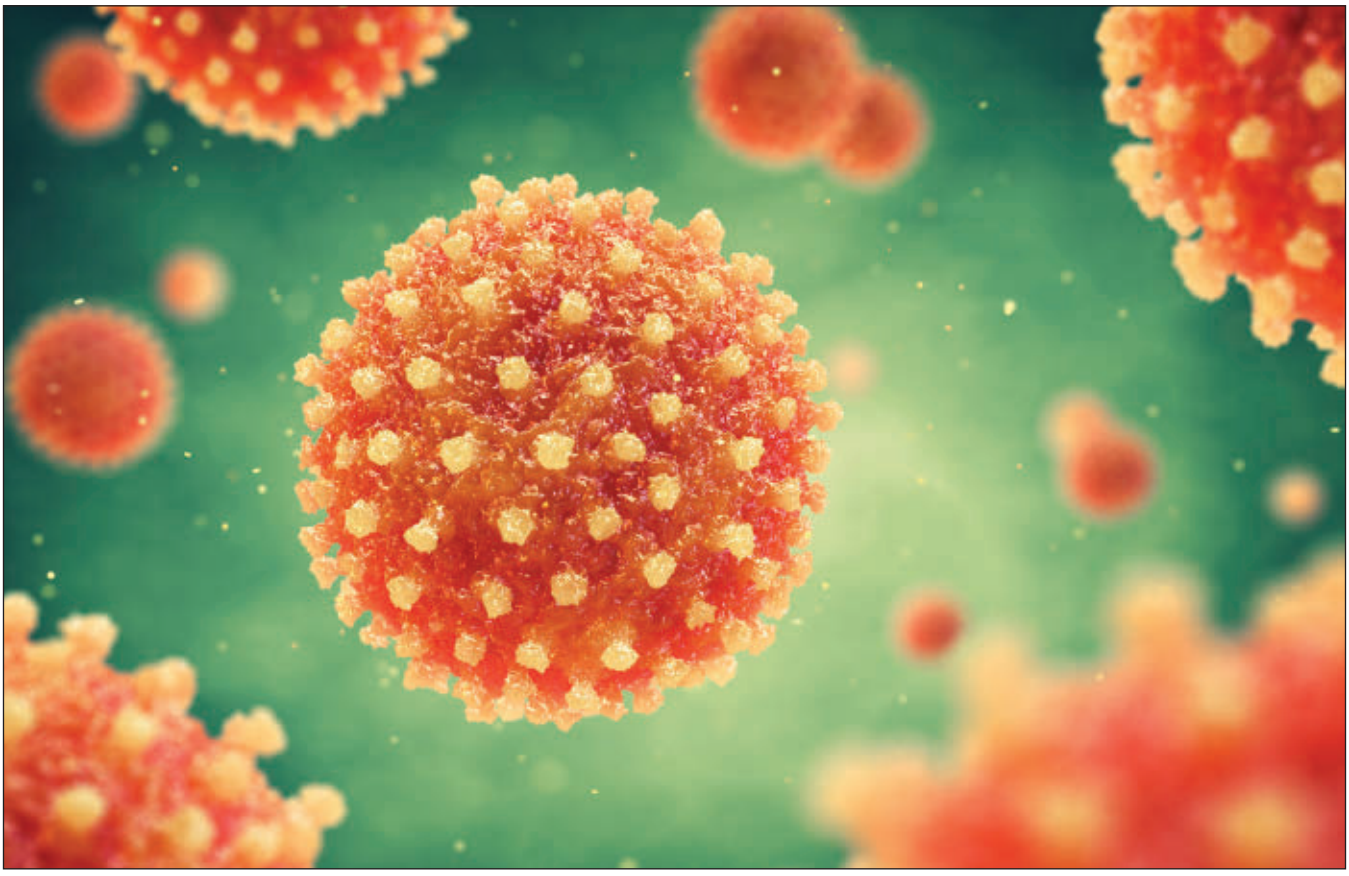
Retail food companies are not only the final step in the food supply chain but are also the final defense against foodborne illness outbreaks. If retail food companies follow the five best preventive practices, they can manage food safety risk at a high level. These "Five Preventive Food Safety Risk Processes" require companies to:

- Use the best personal hygiene practices
- Cook food to the proper temperature
- Hold food at the proper temperature
- Use clean and sanitized equipment to prevent cross-contamination
- Purchase food from safe sources

To execute these practices, you need the right people, processes, equipment, and facilities. If you as a company can do this, you will be in a better place as you mature as a foodservice provider. It may not be easy or cheap, but creating a culture of food safety in your company from the top down will allow these practices to become part of your everyday process and help you succeed in your retail food safety program. ■

We would like to thank all the panelists for their insightful comments and engaging discussion. A special thanks to the staff at the Florida Department of Agriculture and Consumer Services and the Kansas Department of Agriculture for providing input into the AFDO answers.

By David Stumbo, Ed.D., OHST, and Rifath Ali, M.D., M.P.H., M.Sc.



Hepatitis A Exposure among Foodservice Workers

A record hepatitis A outbreak in Kentucky has indicated that foodservice workers (FSWs) have been largely overlooked as an exposed group. While FSWs have not typically been considered to have an elevated risk of infection by some authorities, data specific to the occupational exposure of FSWs to hepatitis A are limited. Additionally, meaningful guidance for the protection of FSWs from occupational infection is lacking. These factors, along with the substantial economic burden faced by FSWs should they become infected, support the need to consider these employees at risk of occupational exposure and infection, to develop and provide specific guidance for their protection, and to conduct better surveillance on their exposures and infections.

Employee protection should be a high priority for foodservice establishments

Overview: The Risk to Foodservice Workers

This outbreak of hepatitis A in Kentucky has heightened attention on the control and prevention of this disease. While the state has typically averaged around 20 acute cases annually, a dramatic increase occurred in 2017, prompting the Kentucky Department of Public Health to declare a statewide outbreak.[1] On June 28, 2018, officials reported it to be the most severe outbreak on record for both the state and country, with the count up to 969 cases.[2] The majority of cases were reported in Jefferson County,[3] home to the city of Louisville. Groups affected by the outbreak include homeless persons, drug users, and healthcare providers.[4,5]

This review focuses specifically on FSW exposure to hepatitis A. Specific instances of FSWs affected by the outbreak include employees of Old Chicago Pizza, Hard Rock Café, and Panera Bread.[6–8] Arkansas and Indiana have reported recent cases among restaurant workers as well.[9] Cases such as

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these and a review of associated literature indicate the need for a greater emphasis on protecting FSWs from occupational exposure to hepatitis A.

What Do We Know?

Hepatitis A viruses are shed in the feces of infected persons and then find their way to other hosts through a range of unhygienic pathways.[10] Person-to-person transmission through the fecal-oral route is considered the primary mode of infection in the United States, with exposure to contaminated food or water a common cause of outbreaks.[11] The U.S. Centers for Disease Control and Prevention (CDC)'s National Outbreak Reporting System notes that from 2000 to 2016, there averaged about three outbreaks of foodborne hepatitis A per year nationally.[12] A foodborne outbreak in 2016 resulted from frozen strawberries imported from Egypt and distributed to California, New Jersey, New York, and Texas.[13] Infection through imported foods is a concern for other countries as well, as demonstrated by a recent outbreak in the Netherlands attributed to a raspberry/blueberry product originating from a producer in Bulgaria.[14] With the global food trade projected to increase, the likelihood of a corresponding increase in foodborne illnesses should be anticipated.[15]

"A record hepatitis A outbreak in Kentucky has indicated that foodservice workers (FSWs) have been largely overlooked as an exposed group."

Control Efforts via Public Health Campaigns

Substantial public health campaigns have been undertaken toward hepatitis A prevention internationally and domestically. The World Health Organization collects and disseminates internationally oriented information on geographic distribution, transmission, symptoms, risk groups, guidance, and other key points.[16] Within the U.S., CDC provides similar functionality, gathering and issuing information tailored toward both health professionals and the public in the form of guidelines, statistics, and surveillance among other information (see "A Plan for Protection for Foodservice Workers,"[17] below).[18] CDC has specifically recommended hepatitis A vaccination for all children upon reaching 1 year of age, residents of communities and households with high infection rates, illegal drug users, men who have sex with other men, travelers to countries with high infection rates, persons with chronic liver disease, and those working with infected animals.[19]

The public health alert issued in response to Kentucky's outbreak promoted vaccination in general, washing hands, and cooking food thoroughly as key strategies to guard against infection.[20] As part of control efforts, CDC epidemiologists determined that the viral strain and genotype found in infected persons in Louisville were identical to those found in California and Utah outbreaks.[21] Other public health regions were notified to guard against subsequent outbreaks and ensure the availability of adequate vaccine supplies for at-risk populations.[22]

Several nonmandatory vaccination efforts were launched in response to the outbreak, including the Louisville Metro Department of Public Health and Wellness (LMDPHW)'s administration of nearly 5,000 immunizations at homeless shelters, syringe exchange sites, and a correctional facility.[23] The LMDPHW also partnered with the University of Louisville Global Health Center to offer vaccinations to foodservice and hospitality workers at the subsidized cost of $25.[24] Private-sector efforts targeting FSWs range from offerings of free immunizations to employees[25] to the implementation by McDonald's of a mandatory policy.[26] Although vaccination of FSWs as a group has not been broadly recommended,[27] a mandatory vaccination policy for all FSWs was shown to be effective at reducing infections in St. Louis County, Missouri.[28] Vaccination or immunoglobulin administration as postexposure prophylaxis is recommended irrespective of occupation.[29]

Problems with Data on FSWs

Certainly, FSWs have experienced hepatitis A infection,[30,31] but it is difficult to determine whether the infections originated from occupational or nonoccupational exposures. Occupa-

A Plan for Protection for Foodservice Workers[17]

The following are recommended to help protect foodservice workers from infection from hepatitis A:

- Routine vaccination for employees exposed to raw foods
- Use of gloves when handling raw foods and related equipment
- Proper employee hygiene involving correct washing of hands, even with glove use
- Effective training on all components, proper glove use, hand hygiene, and disinfection
- Methodical disinfection of surfaces according to FDA guidelines

For more information, please see *Retail Food Protection: Employee Health and Personal Hygiene Handbook* at www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113827.htm#personal and *Food and Drug Administration Food Code – 2013,* chapters 4–7, "Sanitization of Equipment and Utensils," at www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf.

tional infections should be understood to be those that occurred solely due to the infected individual's participation in a work-related activity. Two foreseeable routes of occupational infection of FSWs are from the inadvertent ingestion of fecal material carried on food either: 1) after handling the contaminated food or 2) after contacting a contaminated surface in a food preparation area.

The only occupational groups designated by CDC to be at increased risk of infection are persons working with infected primates and those working with hepatitis A virus in a research setting.[11] However, although FSWs have not been designated as being at increased risk, this should not be construed to mean they are *free* of risk. Indeed, data gathered on outbreaks associated with infected FSWs indicate that some employees were most likely infected during the course of their work[32] and that transmission between coworkers had occurred.[33] Other studies suggest that occupational groups at elevated risk also include day care providers, hospital workers who have direct patient contact, and sewage workers.[34,35] Lerman et al.[36] included FSWs among those occupations considered at elevated risk, along with teachers and others.

Relatively few data are available through existing public health surveillance sources regarding cases of hepatitis A that have been contracted through occupational exposures. Keeffe noted that there is a "paucity of epidemiologic data regarding occupational risk to HAV, particularly in the United States."[35] Data gathered by CDC on hepatitis A cases that consider occupational exposure are minimal. Infected persons who are employed in a nursery, day care, or preschool are distinguished, but these data are of limited utility because they aggregate the employment identifier together with the identifier of attendance at these establishments.[37]

"Relatively few data are available through existing public health surveillance sources regarding cases of hepatitis A that have been contracted through occupational exposures."

The U.S. Bureau of Labor Statistics (BLS) gathers occupationally oriented data on cases of infectious disease from employers annually. Reported cases of hepatitis A must meet recording criteria set by the Occupational Safety and Health Administra-

tion (OSHA), generally described as being work-related, resulting in an infection, and resulting in the infected employee missing work or being placed on restricted work duty for at least one day.[38] A search of the BLS's Occupational Injury and Illness Profiles database for case and demographic profiles, 2011–2016, nature-of-condition characteristic, subcharacteristic viral hepatitis, across all ownerships, indicated that no such cases had been reported.[39] This may seem puzzling in light of indications discussed here that hepatitis A infections have occurred among employees, but BLS data have been noted to suffer significantly from underreporting.[40] BLS data reliability relative to hepatitis A cases may be further challenged in light of the estimate that approximately 24 percent of cases may not be identified due to being asymptomatic.[41]

Safety Guidance for FSWs Is Sparse

Like data on occupational exposures, the guidance and information on hepatitis A specific to FSWs are substantially deficient. OSHA, the preeminent authority on employee safety and health, makes scant mention of hepatitis A on its website,[42] and the agency's training module on youth worker safety in restaurants does not address the hazards associated with foodborne illnesses.[43] Meanwhile, more substantive guidance issued by public health authorities is oriented toward preventing the transmission of hepatitis A in general, rather than protecting any particular employee group.[44–46] Other informational sources, such as recommendations issued by the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN),[47] are tailored to the foodservice industry rather than industry workers.

Infection's Financial Impact on FSWs

Fortunately, the common symptoms of hepatitis A such as nausea, vomiting, and diarrhea are transient and do not typically lead to chronic liver disease, and deaths from complications are rare.[48] However, infection can pose a serious economic burden for FSWs stemming from resultant unemployability. Infected FSWs may quickly find themselves without income, as CFSAN has called for symptomatic employees to be removed from work immediately and prevented from returning to work no sooner than 24 hours following the cessation of vomiting and diarrhea, and to be off work for up to 30 days if serving highly susceptible populations.[47] Likewise, literature issued by the Food Marketing Institute has recommended removing infected employees from work until released by a physician or public health department.[49] Discharge from work can be a very significant consequence for FSWs, since lost income due to infection has been estimated at $2,500 per worker, excluding medical costs.[50]

Conclusion

In light of their potential occupational exposure, the significant economic impact following infection, and lack of solid data and applicable guidance, it is clear that safeguarding FSWs from hepatitis A should be given more attention than is the case currently. Short of their universal vaccination as an occupational group, efforts should be undertaken to ensure that: 1) improved surveillance of occupational exposures and infections of FSWs is conducted by responsible authorities; 2) FSWs are considered at risk of infection as a function of their work by authorities and employers; and 3) occupationally oriented approaches are incorporated into efforts intended to protect their health. A subsequent article will review control methodologies tailored to protect FSWs from occupational exposures to hepatitis A, should vaccination not occur. ■

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By John N. Kinyuru, Ph.D., RNutr, and Jeremiah Ng'ang'a

The Use of Insects as Food Ingredients

An industrial innovation or a food safety concern?

Edible insects are a well-appreciated food source (entomophagy) in many regions of Africa, Asia, and the Americas.[1] In Western countries, the use of insects as food and feed is gaining attention as consumers learn of the nutritional and environmental benefits associated with them.[2] Globally, over 2,000 species are known to be edible and consumed by approximately 2 billion people.[3] According to a global estimation, the most commonly consumed insects by humans are beetles (31%), caterpillars (18%), and bees, wasps, and ants (14%). In addition, consumption of grasshoppers, locusts, and crickets is about 13 percent, followed by cicadas, leafhoppers, plant hoppers, scale insects, and true bugs (10%), termites (3%), dragonflies (3%), flies (2%), and others (5%) (Figure 1).[3]

Insect consumption is usually promoted for three major reasons: nutritional value, environmental benefits, and livelihood improvement (social and economic factors).[4] The nutritional value (relative amount of proteins, fat, vitamins, and calories) compares favorably with that of meat and fish[3] and can reduce nutrient deficiencies in populations consuming them. Furthermore, edible insects can be used in fortified blended foods in countries with food insecurity mainly because of their high protein and micronutrient content and the high bioavailability of nutrients.[5] In terms of environmental benefits, insects emit less greenhouse gas and ammonia[6] as they are mostly omnivorous and therefore could be raised on various organic waste/agricultural side streams. Edible insects have also been reported to contribute significantly to food security and livelihoods in most African countries where they are consumed. For instance, some communities trade the harvested insects to nearby markets, generating income to improve their livelihood.

The demand for affordable, alternative, and sustainable protein sources is surging globally due to the increase in the world's population, which is projected to reach 9.7 billion by 2050. From this perspective, the Food and Agriculture Organization (FAO) of the United Nations proposed a global initiative to increase use of insects as food and feed to ensure future

There are only two kinds of food companies:

Those that *have* had a recall and those that *will* have a recall.

So said an FSIS official speaking to a gathering of meat industry execs shortly after the infamous 1997 Hudson Beef recall, still one of the largest in history. At first, the USDA ordered Hudson to recall 20 million pounds of ground beef. Soon, the number rose to 25 million pounds and at least 16 people were sickened. The most crippling effect was not direct recall costs or even the loss of Hudson's corporate reputation. The loss of Hudson's best customer, fast-food giant Burger King, was the unrecoverable blow.

Since then, the search for solutions that might prove the FSIS official was wrong has consumed billions of research dollars. HACCP was born and government regulations designed to help prevent illness and death have greatly expanded. Recalls, both voluntary and ordered, continue. Today, the Hudson recall is still the fifth largest in history. New and tighter regulations have been published by the USDA, making compliance even more difficult but critically important.

What has the industry learned?

The meat and poultry industry soon learned that multiple hurdles were required to effectively combat such deadly scourges as *E. coli* O157:H7 and its half-a-dozen related STECs, and the various strains of *Salmonella*, *Listeria* and *Shigella*.

> **"For some time, we have been warning food industry companies, specifically meat and poultry companies, about the necessity to appropriately protect themselves and their brands against the increasing risks posed by *Salmonella* recalls."**
>
> ***- Shawn Stevens, Nationally-recognized food industry lawyer***

Of course, proper temperature controls are necessary and frequent testing of raw materials and finished product help prevent tainted foods from reaching the public. There are dozens of 'hurdles' that can be used as part of your HACCP plan, though; all widely promoted by supplier companies. Some require labeling changes, others are expensive and demand costly processing modifications. Almost all of them can run afoul of the increasing consumer demand for natural foods.

What can the industry do to protect itself and consumers?

Intralytix, a Maryland-based research company, suggests using highly effective bacteriophage-based interventions to fight foodborne illnesses. Research conducted by the company and dozens of universities show bacteriophages can provide a natural, non-toxic, safe, and effective means for significantly reducing or eliminating pathogenic contamination of foods.

"We've had great success with products like EcoShield™ and SalmoFresh™," said Director of Intralytix Food Safety Division, Greg Strang. "One plant, which had seen a consistent 35-40% positive rate for *Salmonella* contamination, began using SalmoFresh as an added hurdle and the number dropped to zero during the first four months. Our research says our bacteriophages can reduce the number of positives by at least 80%. We're certified Kosher and Halal, Our products are organic and have no organoleptic side effects, too"

Where can the industry learn more about bacteriophages?

Contact the team members at Intralytix. Greg Strang can be reached at 443-863-6946 or gstrang@intralytix.com

intralytix
SAFETY BY NATURE®

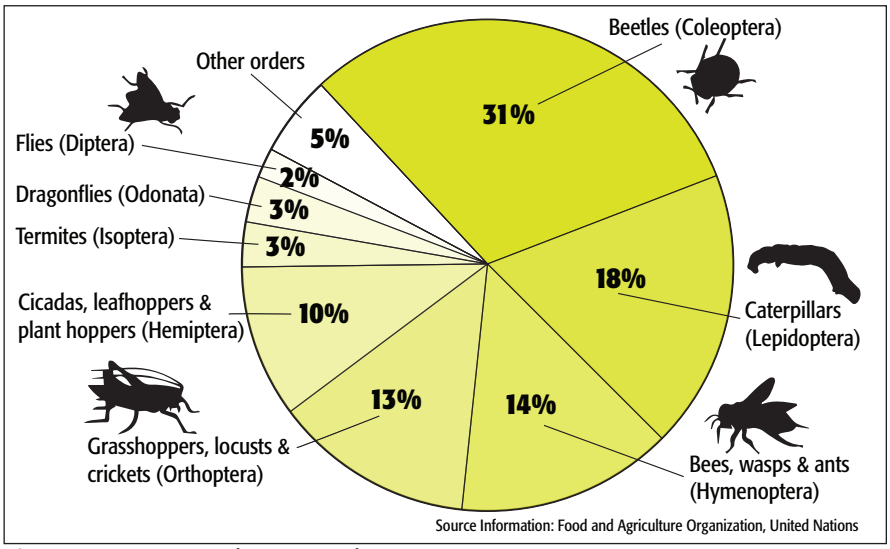

Figure 1. Most Commonly Consumed Insects

food security.[3] The potential of insect food has generated global interest to develop and use insect-food products, such as those shown in Figure 2, and has promoted more research and development on edible insects. Since many countries have a history of using insects as food, this traditional knowledge should be an essential contributor to the future development of insects as a food ingredient worldwide.

*Figure 2. Cricket (*Acheta domestica*)-Based Lollipops Made by Giulia Tacchini*

Risks Associated with Edible Insects

Just like vertebrates, insects can contain biological agents and substances that can represent a health threat to consumers. In an opinion on the risks associated with using insects as a food and feed, the European Food Safety Authority[7] concluded that the risks highly depended on the species of insect, the feed they consume, environment they inhabit, and the production and processing methods adopted. This complexity is the reason consumers are advocating for assurance of the safety of edible insects. The risks can be greater when edible insects are harvested from the wild, as is the case in most African countries. This makes it difficult to control the hazards emanating from the food that the insects consume in the wild. However, in most European countries, or in cases where the insects are farmed, the insects are reared in controlled environments, in which sanitary techniques are usually employed, thus reducing some hazards such as microbiological contamination.[8] Therefore, the differences in the habitats the edible insects are harvested from can contribute to differences in their safety.

Microbial Hazards

Insects both collected in nature and raised on farms may be infected with pathogenic microorganisms, such as bacteria (*Staphylococcus*, *Bacillus*, *Campylobacter*, *Pseudomonas*, *Micrococcus*, *Acinetobacter*, *Proteus*, *Escherichia*, Enterobacteriaceae, and other spore-forming bacteria), viruses, fungi, and protozoa.[9] However, specific studies on the microbiological safety of insects specifically reared versus wild-harvested for food or feed production are rare in the scientific literature.

In West Africa, three rhinoceros beetle species of the genus *Oryctes* are commonly consumed: *Oryctes monoceros* and *Oryctes owariensis*, which breed in dead-standing coconut and oil palms, and *Oryctes boas*, which is found in rotting vegetation and manure heaps. Pathogenic bacteria including *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Bacillus cereus* that may pose a risk to the health of consumers have also been reported in association with these insects.[10] In Botswana, the inner flesh of the wild-harvested mopane caterpillar, *Imbrasia belina*, has been observed disintegrating due to mold growth with fungal isolates *Aspergillus*, *Penicillium*, *Fusarium*, *Cladosporium*, and *Phycomycetes*.[11] Wild-harvested raw grasshoppers (*Ruspolia differens*) from Eastern Africa were found to be highly contaminated by Enterobacteriaceae, lactic acid bacteria, yeast and molds, and bacterial endospores.[12]

A study on four farmed commercial insect species (superworm larvae, mealworm larvae, greater wax moths, and house crickets) showed a high total microbial charge (10^5–10^6 CFU/g) on samples originating from a closed-cycle farm. It was mainly composed of Gram-positive bacteria (fecal and total coliforms). However, *Salmonella* spp. and *Listeria monocytogenes* were not isolated from the tested samples. Similarly, in fresh-farmed insects (mealworm larvae, house crickets, and *Brachytrupes* spp.), spore-forming bacteria and Enterobacteriaceae were isolated.[9] Furthermore, a study in Belgium reported high microbial contamination in mealworm larvae (*Tenebrio molitor*) and crickets (*Acheta domesticus* and *Gryllodes sigillatus*), with average counts for both types of insects above 7.6–8.8-log CFU/g. The identified bacteria include Enterobacteriaceae, lactic acid bacteria, yeast and molds, and aerobic bacterial endospores.[13] A study involving *A. domesticus*, *Gryllus assimilis*, *Gryllus bimaculatus*, *Locusta migratoria*, *Blaptica dubia*, *Galleria mellonella*, *Chilecomadia moorei*, *Pachnoda marginata*, *T.*

molitor, *Zophobas atratus*, and *Apis mellifera* reported the presence of *B. cereus*, *S. aureus*, *Escherichia coli*, *Salmonella*, *Shigella*, and *Campylobacter*.[14]

In a risk assessment study in the Netherlands,[15] the results of a small-scale survey on the microbiological status of 55 insect products (locusts, lesser mealworms, mealworms, and a mealworm snack) that had undergone no treatment apart from freeze-drying found that 59 percent of the insect products exceeded the process hygiene criterion for aerobic bacteria in raw materials used in meat preparation (10^6 CFU/g), while the concentration of Enterobacteriaceae in 65 percent of the samples exceeded the criterion for raw materials used in meat preparations (10^3 CFU/g). The study investigated the presence of *Clostridium perfringens*, *Salmonella*, and *Vibrio*, and none of these were detected. In 93 percent of the samples, the concentrations of the spore-forming bacterium *B. cereus* were less than 100 CFU/g.

Chemical Hazards

Like products from other animals, insect-derived food and feed products may contain hazardous chemicals. Some of these chemicals may be present in the substrates for insects, such as environmental contaminants like heavy metals, organochlorines such as dioxins, mycotoxins, and plant toxins, for example.

"The demand for affordable, alternative, and sustainable protein sources is surging globally due to the increase in the world's population..."

Harmful metals from the environment have been found in the insects' fat, exoskeleton, reproductive organs, and digestive tracts, where they accumulate. Concentrations of heavy metals in insects depend on the characteristics of the elements and their concentrations in the substrates, the insect species, and their growth stage. However, there are limited data available regarding the influence of different substrates on the heavy metal concentration in farmed insects. A study on the yellow mealworm (*T. molitor*) and black soldier fly (*Hermetia illucens*) larvae showed that the insects accumulate cadmium, lead, and arsenic when they feed on contaminated substrates, such as organic matter in soils that contain these metals.[16] The European Union specified the maximum content for cadmium in feed materials of animal origin to be 2 mg/kg (88% dry matter); the insect samples analyzed had concentra-

tions below this limit. High lead content was found in dried grasshoppers, and the dehydration increased lead concentration, while extreme accumulation of selenium was found in *T. molitor* larvae.[16]

Pesticides used against invading insects are potentially dangerous for consumers, particularly if the insects and insect products have been obtained by wild harvesting rather than controlled farming. It is a real problem in some developing countries, where edible, even dead insects, mainly locusts and grasshoppers, are collected and consumed after insecticide treatment. For instance, according to a study in Kuwait, the collected locusts contained no chlorinated pesticides, but a relatively high amount of organophosphorus pesticides were found, possibly due to the pesticides that were used in that area.[17] However, in cases of pesticide treatment, only about less than 0.1 percent of pesticides applied reaches the target pests; the remaining 99.9 percent moves into the environment and may accumulate in the beneficial biota, soil, and water, therefore accumulating in edible insects through the substrate used for feeding.[18]

"Just like vertebrates, insects can contain biological agents and substances that can represent a health threat to consumers."

Information is scarce on the mycotoxin contamination of edible insects. Low levels of aflatoxin B1 were reported in edible stinkbugs that were collected in the forest and stored in traditionally woven wooden dung-smeared baskets and gunny bags previously used to store cereals.[19] Aflatoxin contamination was reported in edible mopane caterpillar (*Imbrasia belina*), and the level of total aflatoxins varied from 0 to 50 µg/kg of product.[11]

Efficacy of Processing Methods in Reducing Risks

Processing of edible insects can help lower the microbial load and the chemical hazards present in the insect. In addition, processing could increase the acceptability, palatability, and digestibility of insects and insect-based products. A recent study showed that drying, boiling or blanching, roasting, frying, fermenting, smoking, and milling of dried insects are the most commonly used processing methods.[20] The processing methods can be applied solely or in combination; for example, boiling preceded most of the other processes like frying, roasting, and drying.[20]

When wild-harvested grasshoppers (*R. differens*) were either deep-fried, smoked, or toasted, Enterobacteriaceae and lactic acid bacteria were completely eliminated, while bacterial endospores were not, highlighting the importance of good handling practices during harvesting and transportation.[12] Another study reported that boiling followed by open-pan roasting and hot-ash roasting of mopane worms is the most effective process to reduce microbial contamination.[20] In addition, a combination of wet heating and dry heating (boiling and open-pan roasting) as compared with dry heating (hot-ash roasting), as well as hygienic handling (using gloves during degutting), helped lower *E. coli* and *S. aureus* in mopane worms.[21] Normally, dry heat is usually associated with a lower heat transfer rate that will be insufficient in eliminating some the bacteria.

A study on the effect of processing fresh samples of farmed mealworm larvae (*T. molitor*) and house crickets (*A. domesticus*) showed that a short heating step was sufficient to eliminate Enterobacteriaceae, while spore-forming bacteria were not eliminated.[9] In addition, simple processing methods such as drying/acidification were considered promising in controlling Enterobacteriaceae and bacterial endospores.[9]

When the effects of blanching (for 10, 20, or 40 seconds), followed by either chilled storage or industrial microwave drying, on microbial counts of yellow mealworm larvae (*T. molitor*) were studied, considerable log reductions were obtained (total viable count, Enterobacteriaceae, lactic acid bacteria, yeasts and molds, and psychrotrophs) at whatever time applied, except for aerobic endospores. No major growth was observed during subsequent chilled storage for 6 days, while blanching for 40 seconds followed by industrial microwave drying for 8, 10, or 13 minutes did not yield larvae with a water activity below 0.60, which is necessary to eliminate all microbial growth.[22]

A study that characterized the effects of different household cooking methods (boiling, panfrying, vacuum cooking, and oven cooking) on the microbial load and nutritive value of mealworms, with a focus on protein digestibility and fatty acid composition, showed that boiling and cooking under vacuum were the most efficient techniques to reduce microbial load while maintaining the high levels of protein and polyunsaturated fatty acids of mealworms.[23] Cooking method-related changes were very low on macronutrient content except for panfried mealworms, which exhibited the highest lipid content.[23] A study microbiologically analyzed a total of 38 samples of deep-fried and spiced (*A. domesticus*, *L. migratoria*, and *Omphisa fuscidentalis*), cooked-in-soy-sauce ("tsukudani"; *Oxya yezoensis*, *Vespula flaviceps*, and *Bombyx mori*), dried (*A. domesticus*, *L. migatoria*, *Alphitobius diaperinus*, *T. molitor*, *B. mori*, *H. illucens*, and *Musca domestica*), powdered (*H. illucens* and *T. molitor*), and other (deep-frozen *B. mori* and honeybee pollen) insect products.[14] Although each product type revealed a microbiological profile of its own, dried and powdered insects displayed markedly higher counts than the deep-fried and cooked ones. All samples were negative for salmonellae, *L. monocytogenes*, *E. coli*, and *S. aureus*, but dried and powdered insects, as well as pollen, contained *B. cereus*, coliforms, *Serratia liquefaciens*, *L. ivanovii*, *Mucor* spp., *Aspergillus* spp.,

Penicillium spp., and *Cryptococcus neoformans*.[14]

Boiling and drying lowered the amount of anti-nutrients (oxalates, phytates) in *Encosternum delegorguei*, while a decrease in the anti-nutritional factors of degutted, boiled, and milled wild-harvested *Cirina forda* (Westwood moth) larvae was reported in Zimbabwe.[24] As shown in the studies above, the processing methods adopted may contribute greatly toward improving the safety of edible insects and insect-based products.

Conclusion

Generally, the levels of hazards are higher in fresh insects than in processed insects/insect-based products. In addition, it's highly likely that insects that are farmed under controlled, hygienic conditions may have lower levels of hazards as compared with wild-harvested insects. However, in the literature, there is little information regarding the hazards related to human consumption of insects. The available information is not very detailed or relies on the extrapolation of information on the consumption of other foodstuffs. Nevertheless, the common processing methods adopted in edible insects (drying, boiling or blanching, roasting, deep-frying, toasting, fermentation, smoking, and milling) are sufficient in eliminating common foodborne pathogens such as salmonellae, *L. monocytogenes*, *E. coli*, and *S. aureus*.

However, using the above-discussed processing methods (e.g., heat treatment below sterilization conditions), spore-producing bacteria may not be eliminated, and the spores may survive and germinate, leading to an important potential hazard–botulism. Thus, whatever way edible insects are processed and whatever insect species is considered, bacterial spores and their survival need special attention. In addition to a thermal treatment, appropriate storage conditions are consequently important. Furthermore, during processing of insects, toxic substances or process contaminants, such as heterocyclic aromatic amines, polyaromatic hydrocarbons, acrylamide, chloropropanols, and furans, can be formed by chemical reactions between the insects and other ingredients. However, this requires further research. Good Manufacturing Practices will be critical in the use of insects as food ingredients to eliminate the physical hazards in addition to biological and chemical hazards. ■

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Future Food Safety Leaders

(continued from page 33)

"As a food safety professional, you need to have all procedures documented, validated, verified, and monitored. It is all valuable. Food safety boils down to doing the right thing and not just relying on regulatory compliance." – Chirag Bhatt

"What makes you the best today is not what will make you the best for your future. You will skin your knees and elbows first and that will make you the best you. Get a coach and mentor and never stop growing. Leadership is a journey, and it never has an ending." – Sharon Wood

"The industry is your 'oyster.' Do your research on careers in food safety and quality. Don't limit yourself to one area. Talk to people, get involved in organizations to find out all the different ways you can use your degree. Join and be active in organizations, committees, and innovation." – Traci Slowinski

"Be proactive. Use skills and abilities to build a strong preventive program and use them to build a robust program." – Ann Marie McNamara

As Brad said to me all those years ago: "Food safety is a BIG responsibility for one person. But a great leader is not determined by the number of direct reports that they supervise; a great leader is someone who can inspire and motivate an entire company to change. I believe *you* are that type of leader." You never know to whom you might be presenting your idea to change food safety culture. It could be a facility manager or the CEO of a Fortune 500 company. *You* can inspire and motivate change. Those were my former leader's words of wisdom that changed my perception of what and who could be a real leader. ■

***Gina R. (Nicholson) Kramer, RS/REHS**, is the executive director of Savour Food Safety International and a member of the Editorial Advisory Board of* Food Safety Magazine.

Product Showcase

Multi-Surface Sanitizing Spray

Sani Professional® has introduced a no-rinse sanitizing multi-surface spray—a complete food safety management system in one product. It cleans. It sanitizes. It disinfects. This all-in-one spray replaces multiple products for cleaning, sanitizing, and disinfecting. It is a cross-contamination food safety management system that is easy and simple to implement across foodservice operations.

Sani Professional, 866.673.4376
saniprofessional.com/

X-Ray Inspection System

Eagle's X-ray technologies, including the Eagle Pack 240 HC with new item-level traceability and the latest material discrimination X-ray technology with new detector configurations and advanced algorithms incorporated into the Eagle RMI 400 system for improved bone detection in poultry products, help manufacturers adhere to continuous improvement programs. These systems reduce product defects, lower downtime, improve yield and giveaway, and protect equipment and extend equipment life across the line.

Eagle, 877.379.1670 • eaglepi.com

Hardware/Software Solution Suite

Avery Dennison is taking a bold step into the future of food that will allow restaurants, groceries, and convenience stores to address current needs and meet future challenges with holistic, scalable solutions for a connected supply chain. The company's FreshMarx® technology harnesses the power of accurate, shared data to enable labor efficiency, food safety, and sustainability, and enhance the consumer experience. The expanding suite of software and hardware solutions is built on scalable technology that is designed to meet the unique challenges and ever-changing needs of food establishments.

Avery Dennison, 800.543.6650 • printers.averydennison.com

Leak-Detection Technology

To help food manufacturers deliver products that are fresh and safe to consumers, avoid premature spoilage, and prevent costly recalls and returns, INFICON has introduced the Contura® S400 leak detector for modified atmosphere packaging as well as flexible packages. This detector is ideal for a variety of dry food applications including coffee, meat, poultry, baked goods, snack foods, confectionary/candy, cheese, grains and cereals, prepared food, and produce.

INFICON, 315.434.1100 • www.inficon.com

Industrial Cyclones

Process equipment manufacturer Van Tongeren America has unveiled a line of industrial cyclone separation systems. Specified to separate dry particles from a stream of air or other gas and remove momentum, the cyclones are custom-engineered for dust collection, particle classification, and/or material recovery to achieve maximum collection efficiency. They are ideal for installation downstream from dryers, coolers, boilers, combusters, and from other dry processing equipment.

Van Tongeren America, 717.450.3835 • www.Van-Tongeren.com

Beverage Transfer Hose

ContiTech has introduced a new beverage transfer hose specifically designed for the wine and brewing industries called Vintner Reserve. This hose is designed to provide the end-user with a lighter, more flexible yet sturdier option for beverage transfer while still maintaining compliance with U.S. Food and Drug Administration and U.S. Department of Agriculture standards. Its flexible construction comes with a redesigned branding consisting of a distinctive gray cover constructed of ethylene propylene diene monomer synthetic rubber. The tube is a smooth white homogeneous liner that does not impact taste or smell.

ContiTech, 888.899.6354 • contitech.us

Temperature Data Logger

Graphic Controls has introduced the TrekTag NFC temperature data logger, which is designed to bring reliability and peace of mind to the customer who requires temperature data they can use to focus on their brand, customers, and bottom line.

Graphic Controls, 800.669.1535
graphiccontrols.com/TrekTag

Please send your product or service press releases and images to barbara@foodsafetymagazine.com.

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Agriculture's Agricultural Marketing Service also monitors pesticide residues in a variety of domestic and imported foods, including fresh and processed fruits and vegetables, as part of the agency's Pesticide Data Program (PDP). EPA uses the PDP data to conduct dietary risk assessments. In addition, the data are used to ensure pesticide residues are at safe levels and adverse health effects are unlikely. The results of the annual PDP are also shared with FDA.

How has the JPA supported food safety for the industry?

Like many products, juice is transported in bulk by tankers. For many years, however, there were no industry standards for the cleaning of tankers used to transport juice. In some cases, transporters would be audited by multiple companies based on different guidelines. This not only caused confusion for transporters and juice producers, it was also costly.

Recognizing the need to establish a standard cleaning protocol for tankers hauling juice and juice products, the juice industry developed the "Model Tanker Wash Guidelines for the Fruit Juice Industry" in 2002.[1] These guidelines are voluntary and assist the industry in maintaining the sanitation and safety of products during transport. Currently, there are 45 tanker wash facilities that participate in the program. These wash facilities are located in the United States, Canada, and Mexico.

The JPA also routinely shares information including federal regulatory and legislative notices with its members to keep them abreast of current rulemaking activities, regulations, policies, and guidance. The association additionally develops resources and best practices to help companies adhere to safety guidelines (see "Resources and Best Practices," below[1,2]). For example, while 100 percent juice is exempt from certain provisions of FDA's Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food (HARPC) rule because 100 percent juice is subject to Juice HACCP, the JPA has developed model food safety plans to guide companies that manufacture juice beverages with how to comply with the HARPC rule. ■

Patricia Faison *is the technical director of the JPA.*

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Resources and Best Practices

Standardized Audits for Wash Facilities

Developed in accordance with the "JPA Model Tanker Wash Guidelines for the Fruit Juice Industry" (Tanker Wash Guidelines),[1] key elements of this voluntary audit program include a standardized audit form, standardized audit protocols, and a list of successfully audited washing facilities. These standardized protocols help companies meet regulatory requirements for safe juice and beverage transportation.

Audit Checklist

Facilities interested in participating in the audit program can also refer to JPA's Tanker Wash Audit Checklist[2] prior to scheduling an audit to verify that appropriate quality, food safety, and security systems are in place to clean tankers.

Kosher Compliance Requirements

As part of JPA's commitment to safe and sanitary juice transport, additional guidelines are provided around kosher compliance. Several rabbinical organizations have agreed that JPA's Tanker Wash Guidelines meet kosher requirements for tanker cleaning and transport. As necessary, juice transporters are encouraged to consult with rabbinical organizations about the transport of kosher products.

JPA Laboratory Proficiency Testing Program

Since 2007, the JPA Laboratory Proficiency Testing Program has been offered to JPA members annually to assess the technical proficiency of their in-house laboratories. A number of analytical tests specific to juices (e.g., pH, titratable acidity, Brix) are performed, followed by a statistical analysis. A report is then generated, demonstrating the results for each participant. Participants are able to evaluate their performance and compare it with their industry peers' performance. This helps companies meet certain food safety and quality certifications, and allows companies to address any deficiencies in testing that may be noted.

Water Data Monitoring

MilliporeSigma has announced a new cloud-based, remote lab water service and monitoring capability available on all Milli-Q® CLX 7000 water purification systems. The Milli-Q Connect online service portal provides digital access to water and system data, allowing users to monitor lab performance remotely and securely. The system facilitates data traceability, audits, and lab accreditation, and the online service portal allows scientists to monitor lab performance with 24/7 remote access and control.

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toxicity data requirements for supporting safety assessments of food contact materials, including impurities. The level of safety testing is largely determined by the cumulative estimated daily intake of a food contact substance. For higher levels of potential exposure to a substance, more toxicity data are needed to support safety. FDA has published a guidance on toxicology recommendations for food contact substances that describes the minimum level of safety testing that should be conducted at various exposures.[10]

Conclusion

As attention on impurities in food contact materials continues, regulatory requirements on how they are evaluated may be on the horizon, particularly in the EU. The European Commission is currently evaluating EU legislation on food contact materials.[11] As part of that evaluation, the advantages and disadvantages of using positive lists of substances that may be used in the production of food contact materials are being evaluated. Likewise, in the U.S., FDA faces increasing pressure about the presence of impurities in food contact materials, with congressional representatives requesting the Government Accountability Office to initiate a review of FDA procedures. ■

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References

1. 21 C.F.R. Section 174.5(a)(2).
2. Carbon black is known to contain polynuclear aromatic hydrocarbon (PAH) impurities on its surface. The regulation 21 C.F.R. Section 178.3297 clears "High-purity furnace black" but specifies that PAHs in this cleared color should not exceed 0.5 ppm and the total level of benzo[a]pyrene should not exceed 5.0 ppb. In contrast, the clearance for channel-process carbon black does not include specifications.
3. FDA. *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations)* (2007).
4. Regulation (EC) No. 1935/2004 (referred to as the Framework Regulation), Article 3.
5. International Life Sciences Institute Europe. *Guidance on Best Practices on the Risk Assessment of Non-Intentionally Added Substances (NIAS) in Food Contact Materials and Articles* (2015).
6. Risk Assessment of Non-Listed Substances and Nonintentionally Added Substances Under Article 19.
7. More recently, EFSA suggested the use of different exposure scenarios for specific populations (e.g., infants and toddlers).
8. FDA's *Chemistry Guidance for FCNs* includes information on CFs in table 1 of appendix IV.
9. www.efsa.europa.eu/en/efsajournal/pub/5708.
10. www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-food-contact-substances-toxicology.
11. ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en.

Focus On: The Hilton College Food Safety Laboratory

At the University of Houston, many of the Conrad N. Hilton College of Hotel and Restaurant Management's 1,000-plus students aspire to climb the corporate ladder at some of the world's top hotel companies, own their own restaurants, or start a craft brewery. Hilton students select an "area of emphasis" during their degree plan in different areas of hospitality, such as casinos, clubs, and cruise ships, but over the past few years, several students have decided to blaze their own path. Under the mentorship of Dr. Sujata A. Sirsat, the college's resident food microbiology professor, these students created a food safety area of emphasis and formed the Hilton College Food Safety Laboratory.

The laboratory positions itself at the intersection of theory and practice. Each member has experience in the hospitality industry, which shapes the group's ability to apply their research. In the past, the lab has studied microbial contamination in hotel rooms, food safety hazards in farmers markets, and beer spoilage. The lab members' eclectic backgrounds help them form a diverse educational and creative environment to expand upon these past ideas and foster the growth of new ones.

After working as a health inspector for 5 years, Ph.D. candidate Karla Acosta decided to take her practical knowledge of food safety legislation and training techniques to the lab. She studies how training professionals can improve the efficacy of food safety programs. As the lab's only Ph.D. candidate, she serves as a mentor to her fellow lab members. Her connections to local public health officials and restaurants prove invaluable when conducting qualitative research, and her expert knowledge of statistical analysis supplements her quantitative methods.

Isabella Raschke, an incoming junior, found herself hooked on food safety after taking Dr. Sirsat's "Safety and Sanitation in the Hospitality Industry" course. Her research interests led her to the beginning of the farm-to-fork chain. Restaurateurs and chefs nationwide are sourcing their produce from soilless farms, and Raschke is determined to develop systems to ensure these growers are following safe handling practices.

Senior Jack Hodges is interested in the way victims report foodborne illness. This past year, he has been developing ways to utilize big data analytics techniques and computer science to monitor foodborne illness reporting in online review forums, such as Yelp.com. He also analyzes trends in the restaurant industry to create tailored food safety training programs for emerging concepts, such as robot-run restaurants.

Alberto Beiza, a first-year master's student, uses his 10 years of restaurant experience to develop realistic simulations in the college's food microbiology laboratory. He tracks the growth of pathogens on common food contact surfaces and subjects them to stressors they may experience in a typical foodservice environment. Using the skills he learned as an art student, Beiza also creates authentic designs and animations for use in the lab's training modules.

Zahra Mohammad, the group's resident postdoctoral fellow, works to improve our food safety knowledge both in the lab and in the field. She develops and delivers food trainings for farmers and food handlers across Texas. Her expertise in working with pathogens such as *Bacillus cereus, Clostridium perfringens,* and *Salmonella* makes her an excellent mentor to the lab's students as they perform microbiological experiments to corroborate their findings.

As the needs of the dynamic hospitality industry change to meet the latest trends and technologies, the laboratory endeavors to stay current. In a city with over 10,000 restaurants, the lab has countless opportunities to apply its findings and trainings. However, the lab hopes to generate tools and publications applicable to foodservice around the world. By combining life science and social science, the Hilton College Food Safety Laboratory aims to change the way we monitor, report, and defeat foodborne illness.

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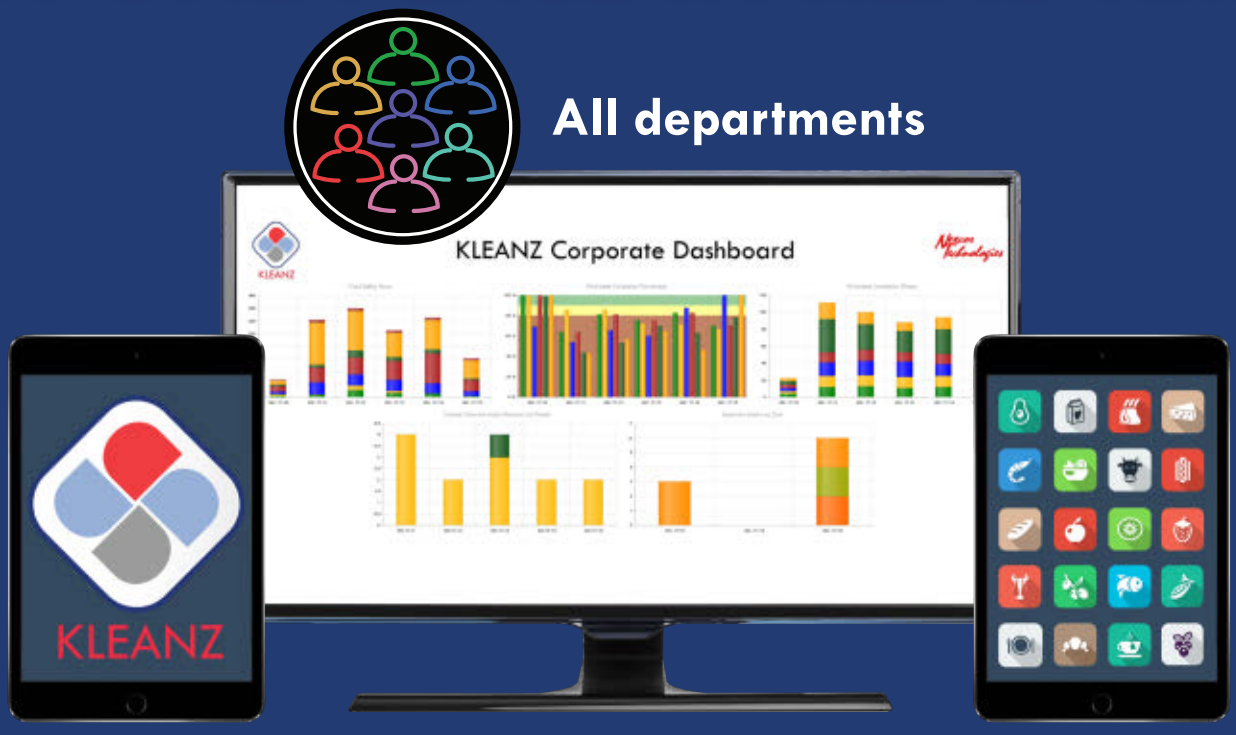

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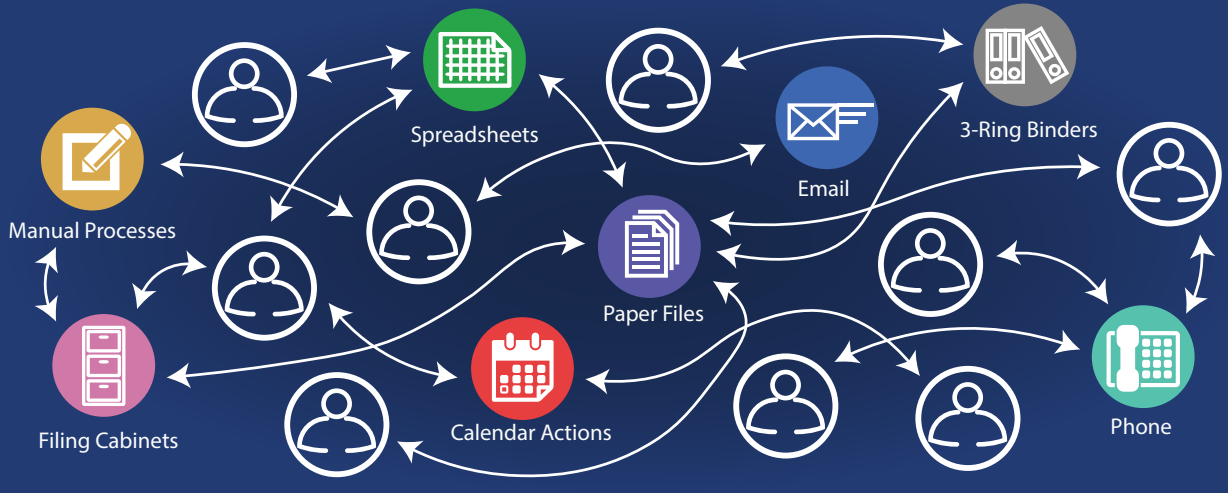

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