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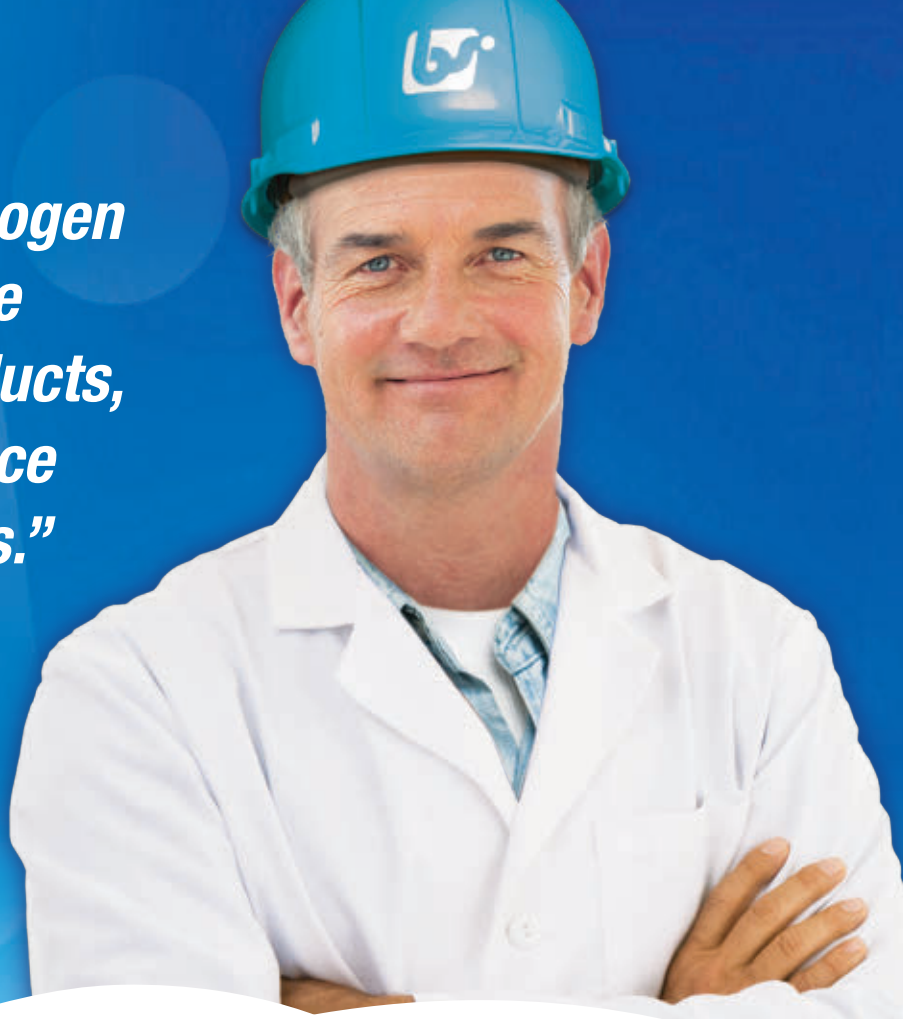

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Editor's Letter

*"Come together, right now…"**

Sometimes it's not obvious that we're all in this together. What with competing products and slogans and aggressive marketing driving wedges between even the most friendly food industry colleagues. But at the end of the day, it's all about collaboration, particularly on best practices: for testing, training, cleaning…the list goes on. Don't believe me? I recently (3 weeks ago as of this writing, though that's hard to believe) came back from the Global Food Safety Conference in Nice, France, where I witnessed competing manufacturers and suppliers and vendors of products and services "come together" for the greater good of food safety. Stories of their journey to certification (specifically those in the Global Markets Program) inspire; their shared frustrations prompt brainstorming and creative problem solving; and their willingness to speak openly and candidly about their perspectives rejuvenates a common purpose of "safe food for people, everywhere."

In fact, it's that very purpose that draws us together across our business battle lines–and makes for some memorable moments, like this: friendly conference attendees from ingredient suppliers (and competitors) Kerry and Givaudan (above).

Not to mention the "coming together" that ensues when you happen to find other food safety folks speaking English (yours truly and the gang from Greenfence) while wandering the streets of Monaco after the closing session (left).

Competition might be good for business and it might drive fast-paced innovation, but when we come together to learn from each other and realize that we all have a common goal–the production of safe food–we actually achieve our objectives faster: Businesses flourish, technology advances, and food safety is improved.

**Apologies to John Lennon*

Best Regards,

Barbara VanRenterghem, Ph.D.
Editorial Director

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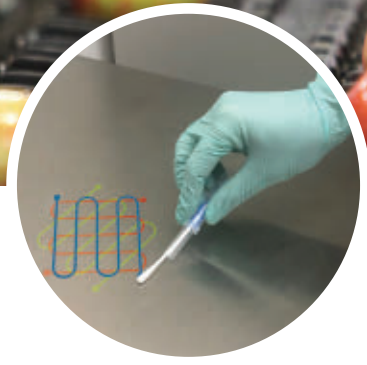

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Bashura Joins *FSM* Board

Jason Bashura has joined the *Food Safety Magazine* Editorial Advisory Board. Jason is a senior manager for global food defense with PepsiCo. Prior to joining PepsiCo, he worked for more than 5 years with the Food Defense Oversight Team at the U.S. Food and Drug Administration, where he was responsible for developing several food defense tools and resources, oversaw grant funding opportunities for state, local, tribal, and territorial organizations, and managed multiple task orders related to food protection-based scientific research in support of the Food Safety Modernization Act. Bashura previously worked as a food biosecurity sanitarian for the Connecticut Food Protection Program.

He serves on the advisory board for the Institute of Food Technologists' Global Food Traceability Center and is a guest instructor at Michigan State University. Jason has an M.Sc. in public health from the University of Connecticut.

FSIS Issues Meat Industry Best Practices for Responding to Customer Complaints

The U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) has shared a new industry resource: the *FSIS Guideline for Industry Response to Customer Complaints 2019*. These guidelines are designed to help meat and poultry establishments develop a written program to respond to customer complaints—particularly those caused by adulterated or misbranded meat and poultry products. The document includes best practices for the meat and poultry industry to follow in such instances. FSIS developed this document in response to an increase in the number of recalls of meat and poultry products adulterated with foreign materials. In many cases, the recalling establishments had received multiple customer complaints prior to these recalls. This document is *not* a regulation. Establishments may choose to adopt different procedures from those outlined in this guideline.

As FSIS continues efforts to improve its industry policies and procedures, the agency is accepting stakeholder comments that may help further advance the current best practices. Comments can be submitted until May 15, 2019, at which time the document will be updated and republished. Refer to the guidelines for more information about how to submit feedback. The guidelines can be accessed at www.fsis.usda.gov/wps/wcm/connect/8d0a0e73-1e6f-424f-a41f-ea942247a5ff/Guideline-for-Industry-Response-Customer-Complaint.pdf?MOD=AJPERES.

FDA Issues Final Guidance on Voluntary Food Recalls

The U.S. Food and Drug Administration (FDA) announced new plans, via the issuing of final guidance, for how the agency will issue public warnings about voluntary food recalls. This new step will help ensure appropriate public warnings and notification of recalls when FDA-regulated products are involved. The guidance discusses how companies can determine whether they should issue a public warning about a voluntary recall. The guidance also describes the general time frame for companies to issue such a warning, what information should be included in a public warning, and situations where FDA may take action to issue its own public warning should a company's warning be deemed insufficient. Details about FDA's policy for moving forward by the posting of recalls to the agency's Enforcement Report are also discussed.

ONLINE & OF NOTE

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The Partnership for Food Safety Education delivers trusted, science-based behavioral health messaging and a network of resources that support consumers in their efforts to reduce risk of foodborne illness. The group enlists more than 13,000 BAC Fighters to help protect public health.

FDA Outlines Strategy for the Safety of Imported Food

The U.S. Food and Drug Administration (FDA) released a new outline of the agency's comprehensive approach to helping ensure the safety of food imported into the U.S. The document is *FDA Strategy for the Safety of Imported Food*.

For imported food, the volume and variety of imports and the complexity of global supply chains make food safety a challenge to address. Further complicating the issue, some exporting countries may have food safety systems that differ from those in the U.S. and differing levels of regulatory capacity. FDA has been provided with a range of tools and authority to address the situation both domestically and in the foreign arena. The strategy document describes how FDA is integrating new import oversight tools with existing tools to help ensure that imported food is safe for consumers in the United States.

The strategy is guided by four goals: that food offered for import meet U.S. food safety requirements; that FDA border surveillance prevent entry of unsafe foods; a rapid and effective response to unsafe imported food; and an effective and efficient food import program.

This strategy document outlines several methods the agency is using to accomplish these goals, including strategies for objectives.

People & Places

SpecPage, a provider of digital product life-cycle management solutions for the food and beverage industry, has announced the appointment of **Brent Cutler** as president and chief operating officer of the Americas.


Cutler


Klinge

Eriez-USA has promoted **John Klinge** to the newly created position of director, strategic sales-aftermarket, and **Charlie Ingram** has been promoted to the newly created position of executive vice president and chief marketing officer.


Ingram

Open-source content management solution provider Magnolia has appointed **Tim Brown** as chief executive officer.

Liphatech Inc. is excited to announce that **Jason Burnette** has been hired as the business director for the company's agricultural division.


Burnette


Orive

The Tetra Laval Group Board has appointed **Adolfo Orive** as president and CEO of Tetra Pak.

Food Safety Net Services has announced that **Victoria Frazier** has been promoted to vice president of sales.


Frazier

Hamer-Fischbein, a provider of bag-closing technology and packaging solutions, recently announced the appointment of former Honeywell International executive **Thurman Melson** to the position of president.


Melson

BizTracks

Kestrel Forms Alliance with Ultra Consultants to Enhance Food Safety Offerings

Kestrel Management has partnered with Ultra Consultants Inc. to provide food safety compliance and remediation advisory services to North American food and beverage processors. The expanded services created through this relationship will help food and beverage processors better select and implement enterprise technology to reduce risk and meet food safety mandates by effectively integrating compliance programs into core business processes and systems.

AOAC and ISO Announce Cooperation Agreement

AOAC International and the International Organization for Standardization (ISO) have announced that they have entered into a cooperation agreement for the joint development and approval of common standards and methods. The partnership significantly increases the global relevance and impact of AOAC/ISO standards and methods.

Please send your press releases to: barbara@foodsafetymagazine.com.

By Erica M. Jackson, Esq., and Caitlin Blanche, Esq.

Recent Support of Proposition 65 Exemption for Coffee Reinforces Need for Science-Based Nutrition Information

Science-based food safety regulations critical to public health

The words "coffee" and "cancer" have been used together in sentences more over the past several years than the coffee industry ever could have contemplated–or wanted. And in light of the current scientific evidence regarding consumption of coffee as it relates to cancer, its distaste for those headlines and that discussion is not unjustified. Recent action taken by the U.S. Food and Drug Administration (FDA), the California Office of Environmental Health Hazard Assessment (OEHHA), and the U.S. Congress illustrate active resistance to state labeling laws that conflict with science-based nutrition information, including California's Safe Drinking Water and Toxic Enforcement Act, better known as Proposition 65 (Prop 65). Prop 65, approved by California voters in 1986, requires warning labels on products sold in California for about 900 chemicals known to cause cancer, birth defects, or other reproductive harm. The statute was amended in September 2016, and the revised regulation took effect August 30, 2018, which only increased the burden on affected companies doing business in California. OEHHA is the agency that administers and enforces the statute in California. The statute itself allows private citizens, advocacy groups, and attorneys to sue on behalf of the state and collect civil penalties and attorneys' fees for failure to provide required warnings. While the statute may have been viewed as well-intended and effective in certain instances, it is now regarded by many as lacking the necessary scientific support and thus unnecessarily burdening businesses, confusing consumers, and, in the instance of misleading food labeling, violating federal law.

Coffee and Acrylamide

Coffee has been targeted by Prop 65 enforcers because of acrylamide, a chemical produced as a by-product of various high-temperature cooking processes (greater than 120 °C or 248 °F), including baking and roasting, particularly with carbohydrate-rich starchy foods but also in the roasting of coffee beans. Prop 65 notices of violation for acrylamide tripled between 2016 and 2017. Discovered in April 2002, the chemical forms in food from sugars and an amino acid that occur naturally in food. The chemical does not appear to be present in uncooked food and is present only at low or undetectable levels in food cooked at lower-temperature processes, such as boiling. Acrylamide generally is not present in food packaging or the environment. Very large doses of acrylamide have been linked to cancer in mice.[1] However, the World Health Organization's International Agency for Research on Cancer (IARC) has concluded there is no consistent evidence that dietary acrylamide exposure at the much lower levels found in food, including through the consumption of coffee, is associated with the risk of any type of cancer in human beings.[2] In fact, IARC found that coffee is associated with a reduced risk for certain types of cancer, including liver and uterine cancer, and there are additional health benefits due to coffee's strong antioxidant effects.

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OEHHA Actions Regarding Coffee and Prop 65

On June 15, 2018, OEHHA announced it was siding with science. It issued a notice of proposed rulemaking, stating, "Exposures to Proposition 65-listed chemicals in coffee that are produced as part of and inherent in the processes of roasting coffee beans and brewing coffee pose no significant risk of cancer." This proposed rulemaking could exempt coffee from Prop 65's warning requirements. A public hearing took place on August 16, 2018, and public comments on the proposed rule were closed on August 30, 2018. OEHHA has not officially commented or initiated rulemaking since then.

FDA Actions on Acrylamide, Coffee, and Prop 65

Since the discovery of acrylamide, FDA has conducted an extensive research program regarding acrylamide levels in food, including an exposure assessment, methodology development, formation and mitigation research, and toxicology research.[3] Through these efforts, FDA has collaborated with international organizations, academia, industry, and a variety of stakeholders to develop knowledge on the chemical. In March 2016, FDA released guidance on manufacturing processes to help growers, manufacturers, and foodservice operators reduce acrylamide levels in food.[4] Consistent with the robust scientific evidence regarding the health benefits of coffee, the current dietary guidelines published by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture recommend that moderate coffee consumption (three to five cups a day or up to 400 mg/day of caffeine) can be included in a healthy diet.

On August 29, 2018, FDA confirmed its position on exempting coffee from Prop 65.[5] Commissioner Scott Gottlieb issued a detailed statement strongly supporting an exemption for coffee from the Prop 65 warning requirement.[6] Part of FDA's mission, he said, is "ensuring that food product labeling doesn't contain false or misleading statements about safety or nutrition. This includes…statements that may be compelled under state law. Simply put, if a state law purports to require food labeling to include a false or misleading statement, the FDA may decide to step in." Commissioner Gottlieb went on to say that a California court's ruling backing a Prop 65 warning for coffee[7] "deeply concerned" the agency and that it strongly supports OEHHA's proposed regulation because it has carefully reviewed the most current research on coffee and cancer, and the science does not support a cancer warning for coffee. In fact, requiring a cancer warning on coffee "could mislead consumers to believe that drinking coffee could be dangerous to their health when it actually could provide health benefits. Misleading labeling on food violates the Federal Food, Drug, and Cosmetic Act."[6]

FDA's recent statements on coffee further emphasize the goals of the agency's Nutrition Innovation Strategy, which was announced in March 2018.[8] The strategy includes a variety of planned actions to help reduce chronic diseases caused by poor nutrition and increase industry innovation in this area. Providing consumers with transparent science-based nutrition information is a hallmark of this strategy.

FDA's recent statements are consistent with its long-standing concerns regarding Prop 65 warnings based on the presence of acrylamide in food, particularly whole grain foods. In 2003 and 2006,[9] FDA wrote to OEHHA, expressing concerns that labeling cereals and some other foods with Prop 65 warnings could confuse consumers and lead to even worse health outcomes. FDA's guidance and letters urged that Prop 65 warnings should not be placed on foods unless science supports such a warning. Despite the specific focus on whole grains, the implications of FDA's position reach to other foods. For example, asparagus, prune juice, toasted nuts and peanut butter, and other fruits and vegetables with known health benefits have also been associated with acrylamide exposure, without any link between actual consumption levels and cancer.

Conflicting Court Rulings on Acrylamide

Despite the current scientific evidence, in March 2018, after 8 years of litigation by numerous coffee companies against Council for Education and Research on Toxics, a California superior court ruled against the coffee companies.[7] The Los Angeles court found that the defendants' experts had failed to convince the court that coffee should be exempted from the controversial statute and that warnings would be required on ready-to-drink coffee. While the ruling itself did not mean coffee causes cancer, media reporting and a general lack of understanding of the statute contributed to further confusion over the safety of coffee. Much protest, debate, and dispute followed, mainly centered on the strong and consistent scientific evidence disproving any link between coffee and cancer in humans. On October 12, 2018, however, 3 days before the trial in the case was scheduled to begin, California's Second Appellate District Court stayed the trial, pending adoption of the new regulation, which would presumably be dispositive of the case. In a separate case in July 2018, a California appellate court sided with 59 breakfast cereal brands in finding that federal law preempts a Prop 65 lawsuit challenging the cereal's lack of warnings due to acrylamide content. The appellate court found that any California-mandated labeling would run counter to federal policy goals aiming to increase Americans' consumption of whole grains. The court relied heavily on FDA guidance and advisory letters in reaching its decision.

Congressional Actions on Prop 65 Enforcement

FDA is not the only authority that wants to see Prop 65 enforcement changed. A bipartisan group of U.S. Congress members have introduced bills in the U.S. Senate (S.3109) and House of Representatives (H.R.6022),

collectively dubbed the "Accurate Labels Act," which seek to ensure that Prop 65 and other warnings are based on sound, scientifically based evidence and risk analyses. If the bills were to become law, Prop 65 enforcement would change dramatically. H.R.6022 has been referred to the House Committee on Energy and Commerce, and S.3109 is before the Committee on Commerce, Science, and Transportation. Regardless of broad industry support, the bills, like those who oppose Prop 65, face a steep uphill battle.

Conclusion

These recent FDA and California administrative actions represent some progress on behalf of the food and agricultural industries, and those siding with science, in the face of a daunting regulation in a huge market. Although some may view it as a broader weakening of Prop 65, it unfortunately is not deterring rampant private enforcement via lawsuits against food and beverage companies. Since the recent amendments to Prop 65 took effect at the end of August 2018, enforcement, including the number of enforcers, has increased as predicted. In fact, the number of notices of violation for acrylamide alone, since OEHHA's notice of proposed rulemaking, has actually increased compared with the same snapshot in 2016 and 2017. More effort is needed to continue the dialogue, and the balancing act, between science-based nutrition and state-regulated consumer advocacy. We will continue to monitor and provide updates on further developments in this area. Stakeholders in the food, beverage, and nutrition sectors should consider engaging with key policy makers to help impact policy outcomes. ■

***Erica M. Jackson, Esq.**, is a partner in K&L Gates's Research Triangle Park and Charleston offices. **Caitlin Blanche, Esq.**, is a partner in K&L Gates's Orange County office.*

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By Karl Thorson and Gina (Nicholson) Kramer, RS/REHS

Reduced Moisture Design & Sanitation: Best Practices

Strategies for minimizing the hazards of uncontrolled water use

Water is fun. It provides nutrients, quenches thirst, and cools us off on hot summer days. Water or moisture is also necessary to support certain types of sanitation. However, traditional wet cleaning methods involve large volumes of water and, often, liquid chemicals. The water and chemicals are liberally applied to walls, equipment, and floors, and then rinsed away with more water. In facilities that make food products with low water activity, this practice increases hazards because water allows microbiological growth and spreads contamination. This article will discuss the application and advantages of designing a reduced-moisture sanitation program that minimizes microbial "bloom" and trims costs.

Treat Water Like Glass

Controlling water should be like controlling glass and brittle physical hazards in a processing facility. We need to take the principles for managing these hazards and apply them to water in our production facilities. Water should be included as a "physical hazard" in the Hazard Analysis of a Hazard Analysis and Critical Control Points plan and a food safety plan. Treat water like glass.

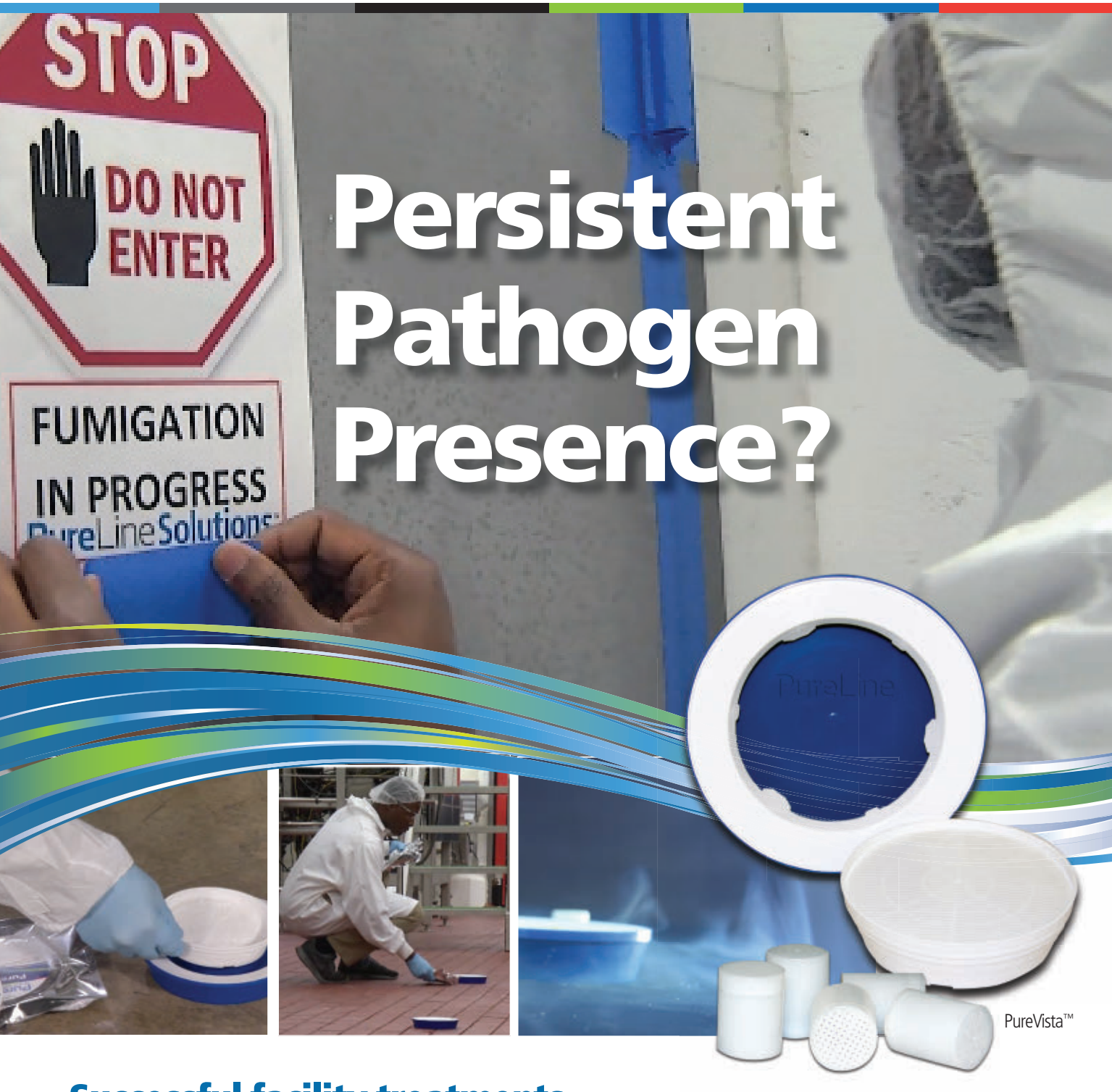
The best way to understand water control is to apply it to our own homes. No one leaves their house knowing that uncontrolled water is dripping, leaking, or producing condensation, or that stagnant water is pooling in our kitchen or home without taking care of it right away. This type of water causes extensive damage to the house with expensive cost of repairs if not fixed expediently. We need to take this same type of thinking and apply it to all food production facilities, making sure that we do not have dripping, leaking, condensation, or pooling of stagnant water in our production facilities. When ignored and not fixed immediately, it creates an environment for microbial growth and damage to the structure and equipment, along with increasing pest activity.

WOW – War on Water

There are many reasons why developing an uncontrolled-water plan is so vital and important to a food production facility. For one, a plan is crucial in making a step change in pathogen risk reduction and spoilage organism control. Uncontrolled water leads to significant microbial growth in food products such as *Listeria*, *Salmonella*, yeast, and mold. Post Holdings has developed great work on "WOW – War on Water" management systems for controlling water within a food production facility, sharing their work throughout the food and beverage industry. These concepts should be applied by all food production facilities.

Uncontrolled water also leads to human safety hazards such as chemical and slip hazards. Beyond the human safety risks, water also poses a risk to production equipment, impacting its reliability and functionality. Even the best-designed equipment is susceptible to water egress, electrical issues, and premature failure. It is important to minimize water's impact to production systems.

Water control is called out as a focus area in the Food Safety Modernization Act. Looking at some of the recent recalls, we see how uncontrolled water has impacted pathogen growth in the environment and how condensation



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contaminates products. The U.S. Department of Agriculture Food Safety and Inspection Service is the only organization that has water and condensation guidance for food production environments in the *Sanitation Performance Standards Compliance Guide*. This guide outlines when condensation is acceptable in food production facilities. In all other environments, uncontrolled water and condensation are unacceptable.

Uncontrolled water also has a negative impact on a company's environmental and sustainability goals. Every food facility has environmental goals based on controlling the amount of water going into the waste system and the cost and impact of treating that water. Sustainability initiatives focus on the use of water within and around a production facility. Controlling water can add value to the company's bottom line.

> "There are many reasons why developing an uncontrolled-water plan is so vital and important to a food production facility."

Water also contributes to contamination risk within all areas of a plant by moving other contaminants around. These contaminants include chemical, physical, and microbiological risks. Unnecessary water is like gasoline for a fire. Facilities should push the concept that water use should be by exception only.

Cleaning Methods That Minimize Water Risk

Figure 1 aligns the cleaning methods applied with the development of uncontrolled-water plans. It shows the levels of risk, from the lowest-risk cleaning activities such as vacuuming and wiping to the highest-risk like high-pressure water and the use of compressed air. The objective is to use controlled methods to collect the soil or material that we are cleaning up, rather than dispersing it into other areas around the facility.

A great analogy is to compare these methods to the types of cleaning we conduct in our homes. We do not dust our living room with compressed air. We need the same type of control in our plants. There might be specific applications for difficult areas to dust, so we might use compressed air in a can to clean keyboards or tight spaces but then would quickly clean up the soil that is dislodged. The same would apply in a processing facility. Only use controlled methods that are applicable to the environment to clean. The same applies to the use of water cleaning. We do not drag in the garden hose to clean the kitchen floor. We control water use with mopping and spot-cleaning. This should also be applied in the plant. We should not be flooding the environment with water but rather controlling the water used to clean equipment, floors, walls, and ceilings, making sure that the areas can achieve a 100 percent dry environment before beginning production. The goal is to minimize the impact, time, and frequency of cleaning that water has on the environment.

Toward More Efficient Changeovers

It is very difficult to drive these types of changes, especially culture changes, of dry cleaning in a food facility. If there is not a food safety crisis or event, the driving factor needs to focus on the positive financial impact of implementing an uncontrolled-water plan. Focus on minimizing the resources and the cost of these cleaning activities to a business. Ultimately, food safety is the driver, but using the financial impact as the force to build the business case for a dry cleaning initiative will gain acceptance and support.

Minimize the disruption of changing the cleaning method by focusing on the goal to be achieved by the cleaning process. Determine the cleaning method to use and the order of preference. Minimize the time for cleaning by following quick changeover (QCO) principles: Get in and out of those activities as quickly and as efficiently and effectively as possible. This can be done by following sanitary design principles. A great tool to use is the Grocery Manufacturers Association's Sanitary Design Checklist both for facility and equipment. It provides a resource to facilitate discussion around sanitary design in developing QCO procedures and processes.

Once the developed methods have been proven to be efficient, focus on minimizing the frequency of cleaning. How long can a run go without stopping for cleaning intervention and then be brought back to a basic condition of

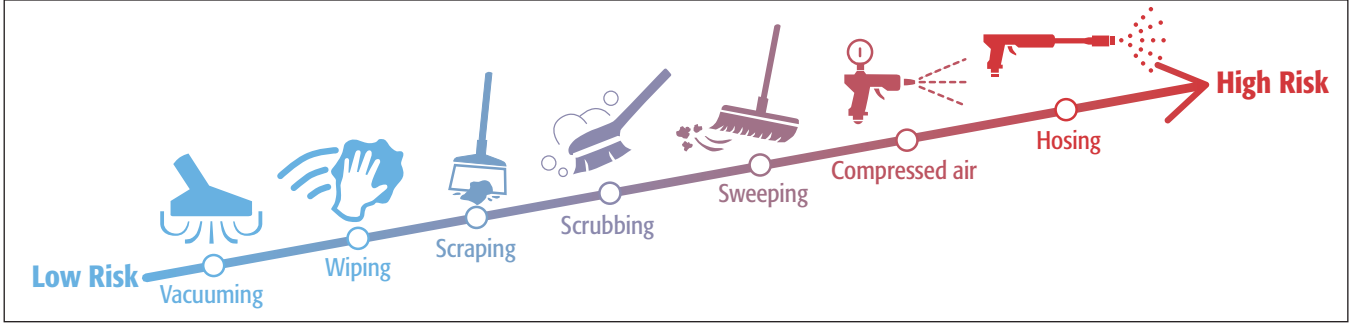


Figure 1. Risks Associated with Cleaning Methods

sanitation and quality? Conduct a comprehensive assessment on reasons to clean. There are reasons to clean beyond food safety and quality. Look at operational needs and plant safety needs. Operational needs include buildup of product on belts causing belt tracking issues, buildup in pipes causing back pressure, and other issues. These same operational needs may also impact human safety issues. Understanding the overall impact for all these reasons is essential in developing a business case for implementing a dry cleaning program.

Order Cleaning Methods by Preference

Give guidance to business team members about the order of preference of cleaning methods selected. The ideal state, when thinking about value-stream mapping, is a no-cleaning scenario. This may seem unreasonable, but there are a few, limited times where this can be applied. The order of preference for cleaning methods to be considered from a financial cost and low-to-high microbial risk is: no cleaning needed, purge, dry clean, dry clean with chemicals, clean in place (CIP), controlled wet cleaning, assisted cleaning system (ACS), controlled CIP, and flood cleaning.

The number one choice is no cleaning needed. This would apply to equipment where there would be redundant or dedicated systems, and where regular cleaning would not be needed. An example of this would be bulk ingredient systems. This would be a regulated system that would not need regular cleaning unless there is contamination or a special event. This applies to bulk materials such as oil, salt, sugar, or even flours if the silos or tanks are designed and maintained appropriately. It can even apply to in-process unit operations. There can be a redundancy in delivery mechanisms to manage for allergens as well. Have a dedicated delivery system for peanuts isolated from a dedicated almond delivery system. These are very stable products requiring little to no cleaning on a regular basis.

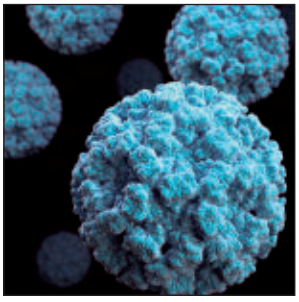
If no cleaning is not an option and removal of soil is needed due to changeover for flavors or ingredients that affect quality of product, purging would be the next cleaning method to consider. The question to consider is, "Can the system get just enough of the next product or ingredients purged to meet the product's sensory needs?" Purging pushes the next product through a pipe using an inert material such as salt or other unique methods. Purging has limited applications owing to not being able to remove 100 percent of the material from the system.

If the need is to remove all the material off or out of the system, then dry cleaning will need to be considered. Cleaning methods such as vacuuming, brushing, scraping, and very limited compressed air use to remove dry soil

(continued on page 64)

By Angela M. Fraser, Ph.D.

Cleanup during a Norovirus Outbreak in a Foodservice Establishment



Decontaminating after an exposure event

Norovirus sickens between 19 and 21 million Americans each year.[1] In humans, norovirus is spread two ways—directly by person-to-person transmission, the most common route, or indirectly through contaminated food, water, or the environment.[2] While environmental transmission is reportedly low (0.35%), emerging evidence suggests contaminated surfaces play a more important role in the spread of norovirus than previously believed.[3] In fact, according to the U.S. Centers for Disease Control and Prevention (CDC), norovirus is the number one cause of diarrhea or vomiting outbreaks spread by direct contact with an infected person *or* through touching a contaminated surface. This is not surprising, given that a single vomiting episode can release 30 million virus particles into the environment.[4,5] Fecal matter contains even higher numbers of particles—10^4 to 10^{11} per gram—with sick individuals producing 500 g/feces per day. Consequently, if contaminated surfaces are not properly cleaned *and* disinfected, these surfaces could be a source of this highly infectious virus, possibly causing or prolonging an outbreak through residual environmental contamination.[6,7]

The relationship between surfaces contaminated with vomitus/feces and norovirus outbreaks has been documented in a number of published epidemiological investigations. For example, in 1999, more than 300 people, over a 5-day period, became sick after one person vomited in the auditorium and bathroom of a concert hall.[8] In a U.S. restaurant in 2006, 364 patrons and employees exhibited symptoms of a norovirus infection after an ill line cook vomited in the kitchen.[9] During October 2009, different groups of flight attendants on the same airplane became sick after a passenger vomited on the airplane.[6] In 2012, 12 employees were infected after a toddler had a diarrheal episode in a car dealership bathroom.[10] The likelihood that vomiting/diarrheal events in food establishments could result in a norovirus outbreak prompted the U.S. Food and Drug Administration (FDA) to add a regulatory provision (2-501.11) to the 2011 Supplement of the 2009 Model Food Code, requiring establishments to have in place a vomit/diarrhea cleanup program guided by 11 elements outlined in Annex 3 of the code. It is important to note that foodservice establishments are *not* required to have an outbreak response program for any foodborne agents including norovirus. However, CDC has published norovirus outbreak management and disease prevention guidelines that establishments could use to inform their outbreak response, including cleanup.[11]

Limitations with Current Cleanup Protocols

Before describing outbreak cleanup protocols, it is important to first briefly discuss three limitations to the current evidence base informing outbreak cleanup protocols, which support the need for additional research to inform effective protocols. First, the lack of a reliable cell culture system for norovirus has been a barrier to the development of environmental disinfectants as mechanisms in which disinfectants work are largely unknown. These mechanisms are typically inferred through studying norovirus surrogates, such as feline cali-

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civirus or murine norovirus. However, no *one* surrogate perfectly mimics human norovirus. Moreover, molecular techniques, such as quantitative reverse-transcription-polymerase chain reaction, are used as part of efficacy studies to detect and quantify the presence of surrogates before and after application of a disinfection strategy. These molecular techniques are limited as they cannot distinguish between infectious and noninfectious virus, so the true efficacy of a disinfectant against norovirus is unknown.

Secondly, the area to be cleaned is based on epidemiological *not* empirical evidence. Cleanup generally focuses on areas known to be contaminated with vomitus and diarrhea. An epidemiological study conducted by Evans et al.[8] reported that a single vomit or diarrheal episode infected 50–70 percent of all persons within a 25-foot radius when pathogen-laden droplets became aerosolized then deposited onto surfaces in the surrounding area. The energy imparted during projectile vomiting can result in aerosol formation during emission as well as when vomitus splatters upon impact.[12,13] Because the full extent of splatter and airborne dispersion cannot be observed by the naked eye, the contaminated area can be surprisingly large. It is unlikely that cleaners would anticipate such large areas of contamination and might not effectively clean because they do not know how large of an area to clean. If viruses remain airborne and/or extend beyond the area cleaned, the duration of exposure could be increased.

Lastly, cleanup protocols typically recommend using a chlorine bleach solution (1,000–5,000 ppm) or a U.S. Environmental Protection Agency (EPA)-registered chemical disinfectant. All of these were tested on hard surfaces using norovirus surrogates; therefore, their efficacy against norovirus in general and on soft surfaces is unknown. This is a critical gap in cleanup protocols as soft surfaces, while disallowed in food production areas, can be common in dining areas in foodservice establishments. Unpublished research findings show that vomiting events frequently occur in public spaces, such as a foodservice dining room, rather than in bathrooms. While most people seek to vomit in bathrooms, this is not always possible, particularly if vomiting is unanticipated. Moreover, cleanup can be challenging on carpet, particularly after a vomiting event, because of the nature of the carpet fibers. Furthermore, using chemical disinfectants on carpet can degrade the fibers, which could be a deterrent for use. One possible solution presented by CDC and the Occupational Safety and Health Administration is steam-cleaning carpet after contamination with bodily fluids, but the efficacy of steam-cleaning carpeting has not been thoroughly tested.

Disinfectants, Not Sanitizers

CDC lists three prevention and control strategies–hand hygiene, exclusion and isolation, and environmental disinfection. The use of a chemical disinfectant is key to interrupting the spread of norovirus from contaminated surfaces during an outbreak. The Food Code defines sanitization but does *not* define disinfection. Both are designed to kill microorganisms but have different applications. First, sanitizers are used on food contact surfaces and soft surfaces, whereas disinfectants are used on all hard surfaces not classified as a food contact surface and *all* surfaces contaminated with bodily fluids. Another difference is that disinfectants are used to destroy or irreversibly inactivate the microorganisms listed on their label, which may include bacteria, fungi, and viruses but not necessarily spores. Sanitizers are used to reduce, but not necessarily eliminate, bacterial count by 5 logs or 99.999 percent. Sanitizers used on soft surfaces must reduce bacterial counts by 3 logs or 99.9 percent. Disinfectants also tend to be used at much higher concentrations and usually have a longer contact time. Sanitizers tend to be used at lower concentrations for a shorter period. FDA clearly states approved concentrations of sanitizers in its respective regulations. Too high or too low of a concentration is a violation of these regulations. EPA maintains a list of registered sanitizers and disin-

Surface	Cleaning Method	How to Make (1 cup = 240 mL)	Strength (ppm)
Porous hard sources, such as wood floors or surfaces visibly soiled with vomit/feces	Chlorine bleach*	1½ cups bleach in 1 gallon water	5,000 (1:10 dilution)
Nonporous surfaces, such as tile floors, countertops, sinks, toilets, and doorknobs	Chlorine bleach*	½ cup bleach in 1 gallon water	1,000 (1:50 dilution)
Food contact items, such as cutting boards	Chlorine bleach* OR dishwasher at 170 °F (76.7 °C)	1 tablespoon bleach in 1 gallon water	200 (1:250 dilution)
Carpet and upholstered fabrics	Hot water and detergent or steam-clean (never dry-vacuum if there has been a diarrheal or vomiting episode)	N/A	N/A

Table 1: Disinfectant Concentration by Surface Type

**Bleach solution must contain at least 5.25% sodium hypochlorite, be prepared fresh daily, and have 10- to 20-minute surface contact time. Use new, unopened bleach for outbreak-related disinfecting (open bottles lose effect after 30 days). EPA-registered disinfectants may also be used, but their effectiveness in outbreaks has not been evaluated.*

fectants on its website.[14] If a product is registered with the EPA and described as a sanitizer or disinfectant, it can be used in a foodservice setting as stated on the label. Check the label to determine the contact time, whether it needs to be rinsed off, and any other precautions to take when handling.

Cleanup Protocols

Note: Universal procedural steps are currently not available for cleaning up a foodservice establishment during an outbreak, making it difficult for the 70 percent of foodservice operations that are independently owned and operated. As a result, there could be multiple interpretations of how to clean up during an outbreak, potentially leading to the ineffective removal of pathogens from the environment.

Once an outbreak has been identified, the facility must heighten environmental disinfection protocols. As it might take several days for confirmation from the local regulatory authority, protocols should be put into action immediately after a suspected outbreak has been identified. While many cleanup protocols specify increasing cleaning and disinfecting during an outbreak, there is no universal standard for the number of times a facility should be cleaned per day during an outbreak. CDC does recommend increasing cleaning areas to twice a day and high-touch surfaces to three times daily. One must consider the highest traffic times in bathrooms and other areas to determine how often to clean each area. The frequency of bathroom and toilet cleaning, especially high-touch surfaces, must also be increased. Lastly, it is important to remember that textile items can also become contaminated and so must be properly cleaned.

Cleaning with a detergent alone is not sufficient to remove pathogens, so surfaces must be disinfected, not just sanitized, following cleaning (Table 1). Sodium hypochlorite (chlorine bleach) has been widely recommended to disinfect human norovirus from surfaces and its efficacy has been well documented.[15–17] Chlorine bleach solution should be applied to hard, nonporous, environmental surfaces at a concentration of 1,000–5,000 ppm. As chlorine bleach may affect fabrics and other surfaces, spot-test an area before applying to any visible surface. If chlorine bleach is not used in the facility, or for surfaces that could corrode or be damaged by bleach, 80 other commercial products have been approved by EPA to be effective against norovirus. These chemicals can be dangerous if not properly prepared and applied. Follow all safety instructions and mix at the manufacturers' recommended concentrations. A list of EPA-approved products is available at

(continued on page 62)

Bob Ferguson

What Industry and FDA Are Thinking about FSMA Implementation – Part 1

Where we are on the FSMA learning curve

Over the past few years, the Food Safety Modernization Act (FSMA) and its resulting regulations and requirements have had an impact on how processors conduct their operations. In June/July 2017, at the onset of the changes spurred by FSMA, and as part of our Food Safety Insights program, we asked processors about their plans for FSMA compliance, how they saw the regulations changing their operations, how they were preparing for FDA inspections, and anything else that they saw that they would be facing.

Now that it's 2019 and processors have had (up to) 2 years of experience with FSMA, we wanted to get an update on how they were dealing with the new rules, what changes they've made, what's working and what's not, and what they've learned about this new regulatory environment.

This is part one of a two-part report on a survey conducted by Strategic Consulting Inc. and *Food Safety Magazine* in January 2019 of more than 180 food processors from 40 U.S. states and 4 Canadian territories, and 60 processors from 36 other countries. We also asked officials at the U.S. Food and Drug Administration (FDA) for their input, comments, and viewpoints. Of the individuals who responded, 82 percent identified their position as quality assurance/quality control, food safety, plant operations, or sanitation specialists, with 18 percent in general management or regulatory/legal affairs or other related positions.

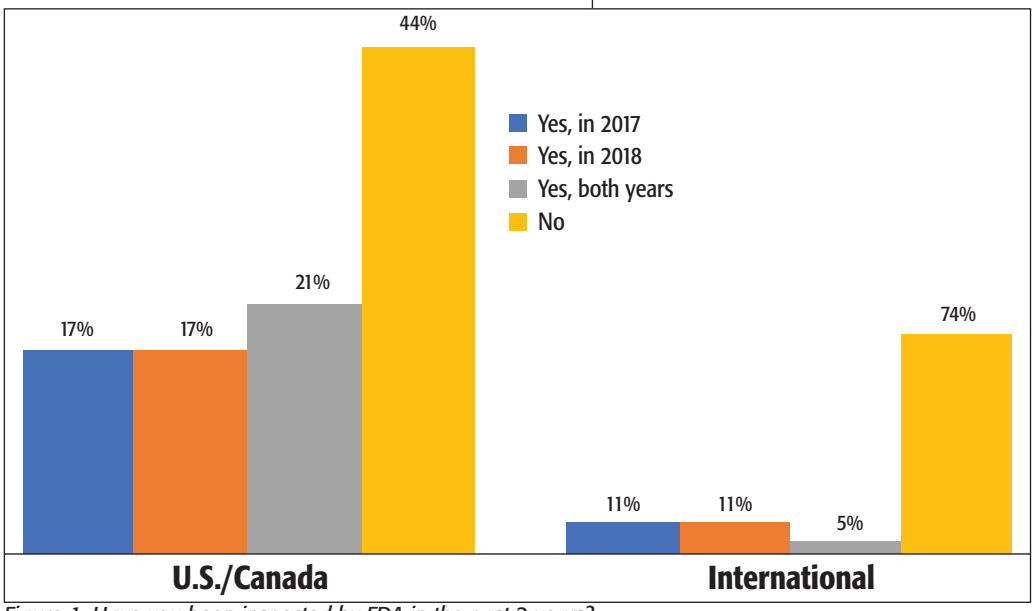

Figure 1. Have you been inspected by FDA in the past 2 years?

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.*

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A Window into Compliance

We asked processors about their efforts to comply with FSMA, their experiences with FDA inspections (if they have had one), what their biggest issues and surprises have been, and any changes that they've made in their environmental monitoring and sanitation programs.

We first asked whether processors had received an FDA inspection in the past 2 years. For those in the U.S. and Canada (Figure 1), roughly one-third said that they have had one inspection in either 2017 or 2018, 21 percent said they were inspected in both years, and 44 percent reported that they have yet to receive a FSMA inspection. It is important to note that we also asked each survey respondent if they were an FDA-regulated facility, and only those FDA-regulated or "dual-regulated" facilities were included in the data. For those processors outside the U.S. and Canada (International in Figure 1), just over one in four had received an inspection, with the rest saying that they have not yet had one.

The data also showed that the likelihood that one had undergone a FSMA inspection was relatively consistent across different types of processors in the U.S. and Canada, with the key exceptions being that more respondents in the processed/prepared foods segment reported having had an inspection in both years than any other category, and more of those in the fruit/vegetable and grain segments reported that they have not yet had an inspection.

In 2017, we asked–ahead of the first FDA FSMA inspections–how processors anticipated that the agency might be changing its enforcement practices and specifically whether FDA would "educate before they regulate" as it was then claiming. At that time, only 40 percent of the respondents agreed that FDA was likely to educate first. Many of the comments we received at the time expressed views such as, *"The inspectors were just in the same new FSMA classes as we were just in, so what can they know about the regulations to 'educate us' that we don't already know?"* and *"What we do is specialized processing with specific unique requirements for our products. How can FDA inspectors, who, because they inspect so many processing plants of varying types, educate us in our processes that they cannot understand as well as we already do?"*

It's now 2019, and, from what we found, something must be going right. In this survey, 72 percent of our respondents in the U.S. and Canada now said that they agree that FDA educates first (Figure 2). In 2017, many of the comments reflected processors' apprehension about what exactly a "FSMA inspection" was going to be. This time, with more than one-half of the respondents having had experience with one or more inspections, many of the comments were far more positive about the FDA and its inspectors. One processor told us that the "*local FDA inspectors in our state have been especially open with us to help with training and to discuss regulatory interpretations with us,*" while another offered, "*I did see that the FDA inspectors were more flexible in discussing the FSMA regulations rather than immediately looking to write up nonconformances. They also seemed to be trying harder to educate themselves as well.*" One particularly positive comment that stood out was from a packaged vegetable processor who said, "*We had a 3-day FDA audit and the auditor was professional and helpful, with no sense that she was there to 'shut us down' or find a problem. We were both well-prepared and had no findings, and the experience was one of our best FDA inspections to date.*"

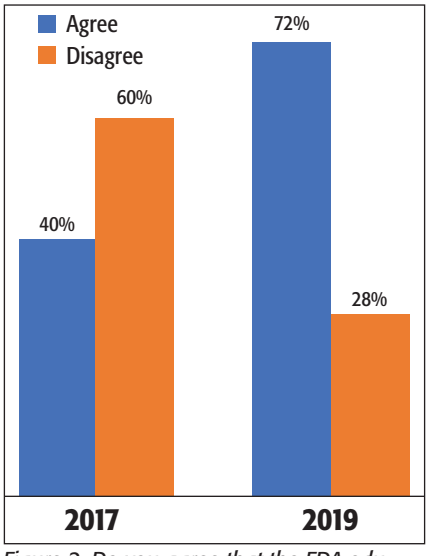

Figure 2. Do you agree that the FDA educates before they regulate? (U.S./Canada)

This is, of course, not to say there were no critical comments. One of the criticisms mentioned, which was a repeat of commentary we heard in our 2017 survey, was the inspectors' lack of specific knowledge about the specific product and processing that was done in the processor's plant. Many had similar comments about the preventive controls training that was available. One ingredient supplier mentioned, *"…honestly, the training is generalized and sometimes hard to take back and implement within your facility and know that you are doing it correctly."* Another mentioned, *"It would be good if (FDA inspectors) better understood where in our specific processes are our real risks, and where in our processes we do not have risks from a food safety perspective, and to put a lesser focus on documentation."*

Many of the comments were in regard to the performance of their local state agencies and the state officials who are doing these inspections on behalf of FDA. These comments were similar to those that we heard about FDA inspectors and, while they contained many critical comments, reflected the same general positive viewpoint as those for the federal agency.

I also had a chance to talk to one state official who said that they give a great deal of credit to FDA for recognizing that it did not have the network itself to get inspections done and fully implement FSMA requirements. The agency's decision to turn to the state agencies greatly expanded FDA's available resources and its ability to get the work done. This official added that they have been able to cooperate with their state university's extension service and use trainers from the university, as well as the ones in their own department, to get the education component involved very early in the process. He added that they were then able to use their own network and inspectors to implement more uniform inspections and compli-

ance throughout the state, and because of this cooperative arrangement, it was his assessment that they had been able to do an effective job implementing FSMA and believes that they are in pretty good shape in his state.

We should also mention that 97 percent of the international respondents (i.e., outside the U.S. and Canada) agreed that FDA first educates before regulating; however, fewer than 30 percent reported having had an inspection. Most of the comments from these processors focused on the great need for additional training to help them comply with FSMA, and many mentioned that they "looked forward" to getting that training. Others mentioned that they were aware that FDA was working with their national agencies, health ministries, and other groups organizing training for FSMA compliance. It was clear, however, that their comments were mainly anticipatory and that few had yet had any formal FSMA compliance training.

> "It was evident from our survey data and interviews that there are some 'growing pains' with FSMA compliance."

Processors List Sticking Points

It was evident from our survey data and interviews that there are some "growing pains" with FSMA compliance. When we asked, "What are your biggest concerns with the implementation of FSMA?" the most frequent answer(s) (Figure 3) was/were related to a better understanding of the regulations and, particularly, interpretations of inspectors' decisions and resolving conflicts with other standards. Many people mentioned conflicts their existing Hazard Analysis and Critical Control Points (HACCP) plan had with the Hazard Analysis and Risk-Based Preventive Controls (HARPC) plan that they had to create. Others mentioned that they need to maintain their HACCP plan to comply with Safe Quality Food (SQF) requirements and how this creates process and plan conflicts that they then need to resolve between SQF auditors and FDA inspectors.

These issues were closely followed by others related to suppliers, including getting suppliers to comply with requirements and getting the proper documentation from those suppliers, with many respondents specifically mentioning having difficulties with the Foreign Supplier Verification Program (FSVP).

Training also showed up high on the list–at fourth with 16 percent of all respondents indicating it as an issue. But it was also clear from their comments that this was not solely due to training materials and programs, but this was also a reference to "internal execution" and specifically *"…getting people to do it that way they were trained."* Many factors about the clarity, quality, and availability of the training were mentioned, although another frequently mentioned factor was related to the processors' own efforts to keep employees properly trained and compliant while facing high levels of employee turnover.

In part two, we will continue to present the findings from this survey and discuss more data about how processors have been modifying their environmental monitoring and sanitation programs to better comply with FSMA. We will also present data from the survey on how frequently FDA is collecting environmental samples.

We will also hear directly from FDA and get their responses to our findings. We asked what processors wished FDA understood better. Not only will we discuss the data from the responses to that question, but we also (anonymously!) showed those responses to FDA and asked for their response as well as what FDA would ask that processors understood better.

I want to close by mentioning that we will be attending the Food Safety Summit in Rosemont, Illinois, in early May, and we will be discussing the findings of this survey at the *Food Safety Magazine* booth. We would like to hear your responses to these data and talk with you about your own experiences with FSMA, and we hope to add those responses in our next column.

See you in Rosemont! ■

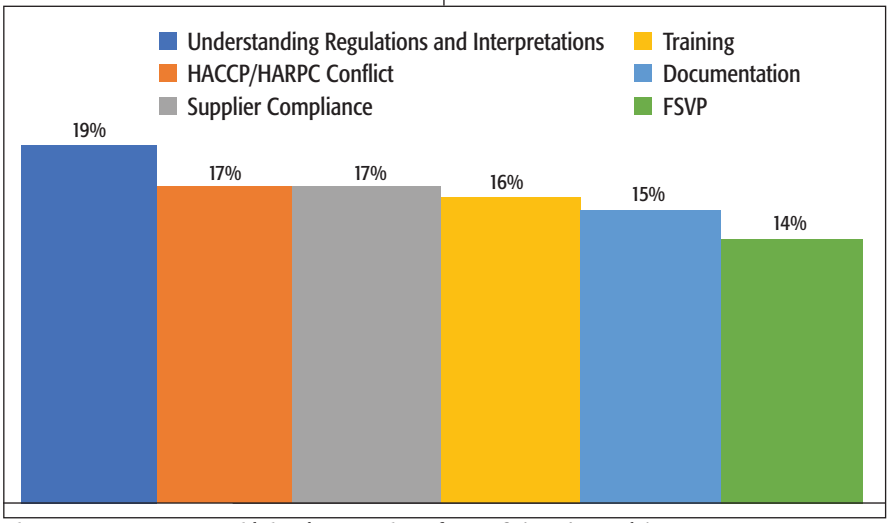

Figure 3. Top concerns with implementation of FSMA? (U.S./Canada)

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

Read more **Food Safety Insights** survey results at www.foodsafetymagazine.com.

Protect Your Brand Using Tips for Effective Sanitation

As most of you have experienced, the Food Safety Modernization Act (FSMA) aims to ensure that the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. Since early 2017, FSMA's emphasis has emerged in the industry via unannounced audits, amped-up third-party audits, or your company's ongoing commitment to Protect Your Brand®. In working firsthand with food production companies, whether it be their management team and/or sanitation team, the following tips will tie in and/or reinforce your priorities on a day-to-day basis.

Biofilm: Biofilm is formed when bacteria adhere to surfaces in an aqueous environment. They begin to excrete a slimy glue-like substance (polysaccharides) that anchor them onto surfaces. Biofilms may be present on floors, walls, pipes and drains, and surfaces on equipment that include stainless steel, aluminum, Teflon, etc. Biofilm-forming bacteria, such as *Listeria*, *Salmonella*, *Campylobacter*, and *Escherichia coli*, are some of the species that dominate these concerns. Independent studies reinforce that the use of high-alkaline and/or high-alkaline, chlorinated cleaners along with a peracetic acid sanitizer is a very good one-two punch that will eliminate biofilms. Let's keep in mind that eliminating biofilms is a process, *not* a one-time application of a cleaner or sanitizer. The key component for cleaning is disrupting the biofilm through some form of agitation, scrubbing, and/or mechanical action. The bottom line is that there are no shortcuts to eliminate this concern.

Sanitation product labeling: It is important to remember that containers of mixed product used throughout the plant must be identified by name along with hazard warnings so they can be traced back to SDSs. Many companies utilize a color-coded product identification system provided by their sanitation supplier. You will also note on these product I.D. cards that many manufacturers include the name, address, telephone number, and website along with the appropriate GHS icon.

Personal hygiene: How often do you explain when, where, and how to wash your hands to your employees? Do you emphasize the importance of taking showers, checking for cuts, wearing clean clothes, pulling back long hair, and removing jewelry? Many people do not realize that the cracks in their hands and fingernails can be excellent carriers of bacteria. As simple as we might think it is to have people regularly and consistently wash their hands, it is equally important that we provide friendly reminders.

Training: Training continues to be the number one priority with sanitation crews. The ever-challenging turnover of employees is an ongoing problem for the majority of production facilities. Our experience indicates that employees better retain information when classroom-type instructions are given in "bite-size chunks" or some form of "snapshot" via PowerPoint-type slides that range anywhere from 10 to no more than 30 minutes. This can be followed by hands-on training in the facility. Safety is typically the number one priority when a company makes sure people have the proper personal protective equipment. Other areas of training will include the seven steps of wet cleaning, including time, agitation, concentration, and temperature. Training on environmental concerns (i.e., *Listeria monocytogenes*) ideally provides employees the opportunity to "think like a bug" as to where some of their harborage points might be and/or how bacteria "hitchhike" around the building.

By providing ongoing training with your sanitation team and/or sanitors, results have shown that your employees will take more ownership with their responsibilities; they will be more dedicated to their work and have a higher attention to detail. This will ultimately allow the production facility to continue producing a quality and wholesome product on a consistent basis.

Effective cleaning procedures: It is important that these procedures are clear and concise. We must be very dedicated to review these steps on an ongoing basis, as they are fundamental to the success of the program. Training the staff on effective cleaning procedures will only enhance the sanitation of the facility, reduce the time to clean, and eliminate waste by ensuring that the application of different chemicals is used in an appropriate manner.

Your sanitation supplier is a terrific resource for training on the chemical use and management of the sanitation program within your facility. Ideally, both parties will have a very transparent form of communication focused on raising the bar of the sanitation program on an ongoing basis. Typically, the goals should be how the sanitation supplier can effectively help you improve your productivity and provide cost efficiencies as you work together as strategic partners. The end result is to make your job easier to perform. As we shared at the beginning of this article, the primary goal is to Protect Your Brand® and/or protect the brand of the companies for which you co-pack. Together, the production facility, the sanitation team, and your sanitation chemical provider will savor the results that we all desire and eliminate the concerns that keep us up at night.

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State and Local Public Health Officials Innovating in Outbreak Investigations

By Randy J. Treadwell, M.P.H., D. J. Irving, M.P.H., REHS, David C. Nicholas, M.P.H., and Steven Mandernach, J.D.

Each year, foodborne illness outbreaks receive extensive media coverage. Typically, the outbreaks that make the headlines are multi-state outbreaks where a group of local, state, and federal public health officials jointly investigate, with federal officials often taking the lead. Each day, state and local officials investigate dozens of intrastate outbreaks with the same level of professionalism and dedication as with a multi-state outbreak. While sometimes these outbreaks are smaller, they still result in significant impact on individuals and communities. This article highlights the work, innovation, and dedication of local and state outbreak investigators in their localized health and agriculture agencies. The innovation and ingenuity at the state and local levels lead to advancements in outbreak investigations on the national level. Even in a multi-state outbreak, these state and local officials are the boots on the ground, providing the information needed to coordinate the national investigation.

An outbreak investigation requires an interdisciplinary approach often referred to as a three-legged stool. Critical for a successful outbreak investigation, the three essential disciplines are environmental health, epidemiology, and laboratory services (see

"Essential Disciplines," p. 30). Each outbreak investigation is different and may require a different level of effort from each discipline. Successfully investigating outbreaks requires strong programs in each of the three disciplines.

This article will focus on outbreak investigations in three states: Washington, Tennessee, and New York. Each investigation has its own unique nuisances and challenges, but there are themes across the outbreaks, including the use of environmental sampling to determine whether relationships exist between the pathogens found in ill individuals and in the environment of the suspected source. Whole-genome sequencing (WGS) has also become an essential tool in outbreak investigations, assisting in determining how closely genetically related pathogens are. This helps investigators determine the likely source of an outbreak and whether cases appear to be linked. Further, the federal government through the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) assist with financial support for state and local outbreak investigations through a variety of funding instruments (see "Programs That Assist State and Local Governments in Outbreak Investigations," p. 36).

Washington RRT: Creating Collaborations to Link Illnesses and Adulterated Product across Time

Washington State has developed and continually improved their food and feed Rapid Response Team (RRT) since 2009. As one of the original states to receive FDA cooperative agreement funding, Washington has worked hard to create a flexible, capable response team to effectively mitigate public health threats associated with human and animal food. The Rapid Response Program, housed within the Washington State Department of Agriculture (WSDA), maintains close collaborative relationships with the FDA Office of Human and Animal Foods Division 6-West (OHAF-6W), the Washington State Department of Health (WADOH), local health jurisdictions in Washington State, industry, and other key partners to help safeguard the food and feed supply.

One such capability of the Washington RRT is to quickly coordinate response partners and leverage their resources to link pathogens found in food samples to human illnesses at the genetic level. These illnesses may even be "historical" in nature in that they may have been reported months or years in the past. However, with stronger technologies and methods such as WGS and bioinformatics, these illnesses can now be associated with pathogens collected from current product and clinical samples to a high degree of accuracy. Linking such illnesses to samples collected during current RRT responses may allow responders to identify chronic issues at a food production facility such as a resident pathogen that is not being killed through current cleaning and sanitation procedures.

This type of "rapid response across time" was exemplified through a multiagency response coordinated by the Washington RRT in September 2017. Eight months earlier, the WSDA Rapid Response Program was notified by foodborne illness epidemiologists at WADOH that two human *Salmonella* Dublin cases with indistinguishable pulsed-field gel electrophoresis (PFGE) patterns and similar illness onset dates had reported consuming retail raw milk from a specific licensed raw milk dairy in Washington State. With proper licensing through WSDA, retail raw milk and hand-skimmed raw cream are legal in Washington State. Approximately 32 firms were licensed to produce and distribute these raw dairy products within the state's borders as of December 2018.

Subsequent sampling of the finished raw milk product processed by the dairy in question did not indicate the presence of *Salmonella*, but rather Shiga toxin-producing *Escherichia coli*. Based on these lab results, the dairy decided to voluntarily recall the implicated lots of their organic retail raw milk in February 2017.

Fast-forwarding to September 2017, routine surveillance sampling conducted by WSDA subsequently confirmed results for the presence of *Salmonella* spp. in retail raw milk product processed by the same firm. This time around, the firm respectfully declined to issue a voluntary recall. Due to the possible public health implications based on the positive sample results, WSDA developed and distributed a public health alert, a public information release that includes the sample results, health information on salmonellosis, and distribution information for the positive product.

Through coordination efforts led by the Washington RRT, the WADOH Food Safety Program notified local health jurisdictions throughout the state and provided them with a copy of the alert to be used as a tool for notifying retail points of sale.

After the four additional raw milk samples were confirmed for the presence of *Salmonella* spp., Washington

Essential Disciplines

Environmental health: Sometimes referred to as sanitarians or environmental specialists. During an outbreak investigation, these individuals typically work with farms, firms, and food establishments and complete on-site investigations and interviews, collect food and environmental samples, and collect trace-back and trace-forward information. Typically, these professionals are employed by state departments of health or agriculture, or local departments of health. The samples provided by environmental health are tested by laboratory services, and the information obtained can help epidemiologists provide additional information to assist in working with ill individuals. Environmental health professionals frequently monitor consumer complaints and food sample and environmental sample results, looking for potential outbreaks.

Epidemiology: Epidemiology in this context is the study of diseases and their causes. Epidemiologists interview those who have become ill with a potential foodborne illness and those with similar exposures, learning details about what they have eaten, where those foods were from, and potentially obtaining purchase records to assist in determining exactly what was eaten and when. Typically, they also work with the data provided by ill and well individuals to determine the most likely potential foods that cause the illness. Information provided by the epidemiologists can be used to help environmental health determine areas of focus for investigation, taking samples, conducting interviews, and gathering additional information. Their work can also assist in prioritizing samples to be collected and tested from ill individuals, foods, and the environment. These individuals typically work in state and local health departments. Epidemiologists frequently monitor surveillance systems such as reportable illness test results, looking for potential outbreaks.

Laboratory services: Laboratorians analyze samples from ill people, foods, and the environment. They look for bacteria, viruses, toxins, and chemicals that may cause illnesses. They type the samples, including the use of whole-genome sequencing (WGS) and pulsed-field gel electrophoresis (PFGE). It should be noted that PFGE is currently being phased out as WGS provides more complete information. In the interim, PFGE can be a fast way to determine whether an organism is related among various samples. The information provided by laboratorians assists both environmental health and epidemiologists in coming to accurate conclusions. These individuals typically work in public health and state departments of agriculture laboratories.

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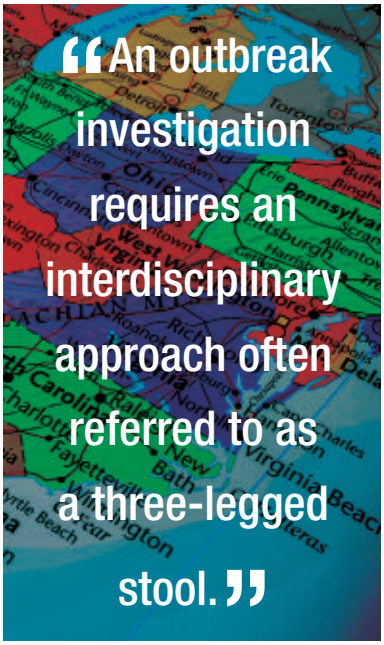
RRT was notified by WADOH epidemiologists that serology identified the pathogens as *Salmonella* Dublin. PFGE patterns were also indistinguishable from both the previous product samples *and* the two human *Salmonella* Dublin cases back in January 2017. The association between a historical illness cluster and a food product was getting stronger.

With this tie between confirmed positive product samples and historical human illnesses, WADOH issued their own public information in collaboration with WSDA. The release stated that health officials urged consumers not to drink the organic retail raw milk with the implicated sell-by dates from the specific dairy. Shortly thereafter, WSDA issued a summary suspension of the dairy's milk processing plant license, therefore administratively halting the ability to legally process and distribute retail raw milk. The dairy's milk producer licenses were not affected by the order, which allowed the dairy to still milk their cows, hold their milk, and divert it to be pasteurized if they chose to do so.

Additionally, Washington RRT and WADOH epidemiologists requested CDC bioinformatics to conduct a genomic comparison of the Dublin isolates. The comparison indicated that all seven samples (five product and two clinical) were highly related to one another within 0–2 single nucleotide polymorphisms.



Leveraging the capabilities of its public health partners and the current gold standard in food safety-related DNA sequencing, Washington State was able to associate human illnesses with a food product and take regulatory steps to mitigate future illnesses. Working closely with the WSDA Food Safety Program, the dairy took specific corrective and preventive measures that hopefully will reduce the risk of product adulteration in the future.

Identifying the capabilities of its response partners and coordinating their deployment to protect public health is a key strength that the Washington RRT brings to an integrated food/feed safety system both within Washington State and nationally. Due to the proactive nature of the public health agencies in Washington State, the newest tools and resources can be effectively utilized to control current public health threats and prevent them from occurring in the future.

Getting to the Problem: Detection of Norovirus in Tennessee

Norovirus is the leading cause of foodborne illnesses in the U.S., with annual illnesses estimated in the millions, thousands of hospitalizations, and hundreds of deaths. The health and economic impacts are significant and keep this pathogen in the forefront of public health efforts. Recent advances in norovirus detection have allowed public health agencies to improve investigation techniques in outbreaks where norovirus is the culprit. Environmental sampling provides a valuable resource in these outbreaks, strengthening the connection between ill people, suspected foods, and environmental contamination.

Norovirus outbreak investigations typically involve three complementary areas: 1) environmental investigations, 2) epidemiological studies, and 3) laboratory analysis of clinical specimens. Sometimes these investigation methods are ineffective in determining etiology and mode of exposure due to people's unwillingness to provide a sample, small sample size for statistical analyses, and/or poor food history recall. Environmental sampling, however, has helped during outbreak investigations with missing data or complemented outbreaks where data from other areas are strong. Environmental sampling for norovirus is a relatively new approach providing an additional tool to help fill informational gaps and aid in determining the cause of the outbreak, while facilitating short- and long-term control measures.

The Tennessee Department of Health (TNDOH) has worked alongside its public health lab to add this tool to its public health toolbox and has collaborated to develop new sampling protocols that include swabbing for norovirus during outbreaks at foodservice establishments (FSEs). The sampling technique and materials used were based on the environmental sampling protocol described in a recent study.[1] TNDOH has used a swab with a tip made from macrofoam—a material proven to be more effective in recovering norovirus from surfaces when compared with materials like cotton, nylon, and traditional sponges. Additionally, macrofoam has proven effective in releasing norovirus particles during the extraction process.

Since testing this strategy, TNDOH successfully detected norovirus in two restaurant outbreaks. In one of these outbreaks, the local health department was notified that a dining party had become ill with vomiting and diarrhea following meals at a restaurant (Table 1). Illness onset, symptoms, and duration were consistent with norovirus. This prompted an environmental assessment at the restaurant, where a food handler was identified as having diarrhea and being present at the restaurant during the period in question. The employee reported having a diarrheal episode in a single-occupancy, unisex restroom that was not used by any members of the dining party. Investigators used this information to determine likely contamination zones and collected 24 swabs in the ill food handler's workstation, the restroom used by the ill food handler, the restrooms used by the dining party, and the private dining area (Table 2).

Epidemiological information for this outbreak was limited to the dining par-

ty. No additional ill or well customers outside the dining party were identified because customer contact information was not retained by the FSE. Therefore, definitive epidemiological studies could not be performed.

Stool specimens were collected from four out of the eight dining party members who reported illness. TNDOH could not obtain stool from the ill food handler. All stool specimens were positive for norovirus GII.2. Of the 24 swabs collected at the restaurant, two were positive for norovirus GII.2, the same genotype the ill customers had. Importantly, both positive samples were recovered from the same toilet area used by the ill chef who reported having diarrhea while working. All samples recovered from the restroom used exclusively by the dining party were negative.

An environmental assessment revealed that reporting and exclusion policies for ill workers needed to be revised. While the restaurant had an ill-worker reporting policy, employees were not well-trained and were not following the policy. Results of the assessment were communicated to the restaurant, which facilitated better understanding of the importance of training and communication of these food worker policies. Furthermore, environmental sample results directed more intensive cleaning and disinfection of contaminated areas.

Environmental testing for norovirus is a valuable tool to support epidemiological and/or environmental data while providing investigators with an improved understanding of how and why the outbreak occurred. In addition, the environmental sampling results have helped focus remediation efforts by the restaurant. Management was informed of specific areas most likely contaminated so that more aggressive disinfection methods could be deployed. These control measures would not have been recognized and emphasized without the evidence provided from environmental sampling. Adding environmental testing for norovirus to the public health toolbox enhances the ability to understand and respond to outbreaks.

Cracking the Case: *Listeria monocytogenes* in New York

Listeria monocytogenes is one of the leading causes of fatal foodborne infections in the United States among patients with laboratory-confirmed infections.[2] Reported outbreaks of *Listeria* infections in the 1990s were primarily linked to deli meats and hot dogs. Today, *Listeria* outbreaks are often linked to dairy products and produce.[3] Compared with other common foodborne pathogens, *L. monocytogenes* has a longer incubation period–typically between 14 and 21 days but can be as long as 70 days.[4] The relatively long incubation period of *L. monocytogenes* makes it difficult to identify the implicated food item that caused the illness. To improve the identification

Norovirus Questionnaire for Ill Employee, Customer, or Suspect

Establishment:
Street:
City: State: TN ZIP:
Outbreak State ID: ☐ Confirmed norovirus ☐ Suspected norovirus ☐ Other etiology
Onset: Date Time
☐ Employee: ☐Server ☐Foodhandler ☐Busser ☐Bartender ☐Other Date/Time worked: Describe Task:
☐ Customer
☐ Ill in establishment ☐Vomiting ☐Diarrhea Date/Time: Location ill: ☐ Kitchen ☐ Dining ☐Restroom
☐ Ill before coming into establishment ☐Vomiting ☐Diarrhea Date/Time Visited: Location visited ☐ Kitchen ☐ Dining ☐Restroom
☐ No Reports of illness in establishment (suspected)
Clean-up: ☐ yes ☐no Method: ☐ ezone ☐steam ☐ chemical chemical name: Nsro approved ☐ yes ☐ no

Swab #	Collection Date/Time	Collection Site Description	Visibly Dirty

Additional comments:

**One of these forms needs to be performed for each ill individual and continue swab number counts to next sheet. Page__of__
**Keep copy of Chain of Custody with this form.
**Check all boxes that apply.

Table 1. Questionnaire Used for Outbreak Investigation

of the source of illness associated with *L. monocytogenes* cases and outbreaks, the New York State Department of Health (NYSDOH) has been actively implementing the use of WGS since 2013 and of environmental sampling as techniques to solve *L. monocytogenes* outbreaks.

In 2015, two *L. monocytogenes* cases were reported to NYSDOH from the same county. Both cases were male, both were in their 70s, one case was hospitalized, and one case was deceased. Both cases were PFGE matches to each other and to other cases nationwide. WGS analysis identified that these two cases were 0–1 alleles apart from each other, but far away from other PFGE matching cases, suggesting a high genetic relatedness. One case and one proxy were reinterviewed with the *Listeria* Initiative Case Report Form, an enhanced surveillance form designed to collect detailed information on listeriosis cases in the United States. Review of the questionnaires

Establishment: Restaurant A
City: Nashville State: TN
Outbreak State ID: TN16-062

Swab #	Collection Date	Collection Time	Collection Location	Test Result	Serotype
1	12/20/16	10:20 AM	Underside of toilet seat in outside unisex restroom	–	
2	12/20/16	10:22 AM	Top of toilet rim in outside unisex restroom	–	
3	12/20/16	10:25 AM	Toilet flush handle in outside unisex restroom	–	
4	12/20/16	10:27 AM	Base of toilet in outside unisex restroom	–	
5	12/20/16	10:30 AM	Restroom door handle in outside unisex restroom	–	
6	12/20/16	10:33 AM	Server touch screen for placing food orders in separated dining area	–	
7	12/20/16	10:36 AM	Hand sink faucet in small auxiliary kitchen	–	
8	12/20/16	10:39 AM	Paper towel dispenser in small auxiliary kitchen	–	
9	12/20/16	10:40 AM	Telephone handle and buttons in small auxiliary kitchen	–	
10	12/20/16	10:42 AM	Light switch in small auxiliary kitchen	–	
11	12/20/16	10:45 AM	Exiting door handle to dining room in small auxiliary kitchen	–	
12	12/20/16	10:48 AM	Control dials on stove in small auxiliary kitchen	–	
13	12/20/16	10:49 AM	Exit door handle to outside from small auxiliary kitchen	–	
14	12/20/16	10:50 AM	Walk-in cooler door handle in main kitchen	–	
15	12/20/16	10:51 AM	Main dining area unisex restroom at end of hall underside of toilet seat	+	GII.2
16	12/20/16	10:53 AM	Main dining area unisex restroom at end of hall top rim of toilet	–	
17	12/20/16	10:54 AM	Main dining area unisex restroom at end of hall base of toilet	+	GII.2
18	12/20/16	10:56 AM	Main dining area unisex restroom at end of hall flush handle	–	
19	12/20/16	10:57 AM	Main dining area unisex restroom at end of hall exiting door handle	–	
20	12/20/16	10:58 AM	Main dining area unisex restroom at end of hall light switch	–	
21	12/20/16	10:58 AM	Main dining area unisex restroom right side of hall underside of toilet seat	–	
22	12/20/16	11:00 AM	Main dining area unisex restroom right side of hall toilet rim	–	
23	12/20/16	11:02 AM	Main dining area unisex restroom right side of hall toilet base	–	
24	12/20/16	11:03 AM	Main dining area unisex restroom right side of hall toilet flush handle	–	

Table 2. Norovirus Environmental Sampling Location and Results

indicated both cases shopped at the same location of Grocery Store A, which has a shopper card program. Purchase histories for both cases were obtained and review of purchase histories indicated that both cases purchased Brand B cheese and deli items from the same deli department within 3 days of each other.

Grocery stores in New York State are regulated by the New York State Department of Agriculture and Markets (NYSDAM). NYSDOH asked NYSDAM to conduct a site visit at Grocery Store A to collect environmental samples at the deli. Twenty environmental samples were collected and submitted to the NYSDAM Food Laboratory for *L. monocytogenes* detection and PFGE. Subsequently, 11 of 20 environmental samples from the deli were positive for *L. monocytogenes*. Among these samples, three different PFGE patterns were identified, and 8 of 11 samples were a PFGE match to the outbreak strain. WGS analyses conducted by NYSDOH's Wadsworth Center identified an environmental sample collected from a cheese tray that was 0–1 alleles apart from the clinical cases, indicating it was highly related and the likely source of illness.

In 2014, a cluster of three *L. monocytogenes* cases with a matching PFGE pattern were identified in County C. Limited information was available for two of three cases; no epidemiological link was recognized at the time and WGS was not routinely conducted then. Late in 2016, County C reported two additional PFGE matching cases; WGS results indicated these two cases were 0–2 alleles apart and highly related to each other. The 2016 cases both reported consuming food from Establishment D. County C initiated an investigation at Establishment D. In January 2017, an additional case with a PFGE pattern matching the 2014 and 2016 cases was identified, and this case also reported consuming food from Establishment D. WGS analyses conducted by the Wadsworth Center indicated that all six cases from 2014, 2016, and 2017 were highly related to one another (exhibiting a 1–6-allele

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- Walnut
- Shellfish
- Fish
- Shrimp
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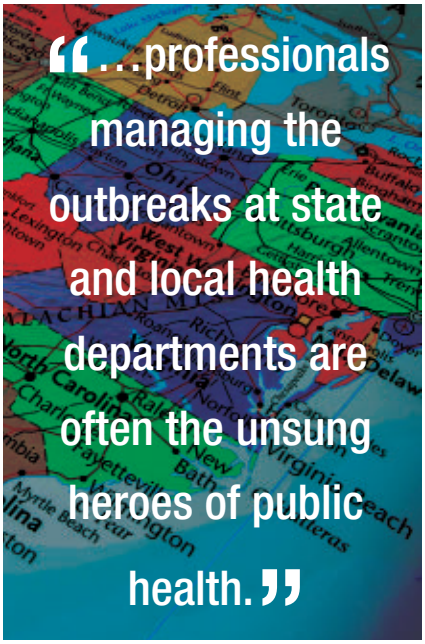
difference). Additional interviews were conducted, with five of six cases reporting consuming food from Establishment D. County C conducted a site visit at Establishment D and collected 20 environmental samples; however, all 20 samples were reported as negative for *L. monocytogenes* by the Wadsworth Center. Per recommendation of the county, Establishment D cleaned and sanitized their entire facility in February 2017.



In May 2017, County C reported another PFGE matching case who consumed food from Establishment D. WGS analysis indicated that this case was highly related to the six previous cases. County C collaborated with the NYSDOH Environmental Health Specialist Network (EHS-Net) program, the New York Integrated Food Safety Center of Excellence, and NYSDAM to develop a new environmental sampling plan. Environmental sampling supplies were provided by the NYSDOH EHS-Net program, and environmental sampling was repeated with assistance from NYSDAM; 42 environmental samples of the food production facility and equipment were collected, and 4 of the samples were positive for *L. monocytogenes*. The four environmental samples were a PFGE match to one another and to the seven clinical cases. WGS analysis

Programs That Assist State and Local Governments in Outbreak Investigations

This list highlights some but not all of the major funding streams that support foodborne illness investigations.

Rapid Response Team Program (FDA)

RRTs are multi-agency, multi-disciplinary teams that operate using Incident Command System/National Incident Management System principles and a unified command structure to respond to human and animal food emergencies. Currently, there are 22 FDA-funded RRTs and 3 unfunded teams (www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/ucm475021.htm).

FoodNet (CDC)

Established in July 1995, the network is a collaborative program between CDC, 10 state health departments, the U.S. Department of Agriculture’s Food Safety and Inspection Service, and FDA. FoodNet personnel located at state health departments regularly contact the clinical laboratories in Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York to get reports of infections diagnosed in residents of those areas. The surveillance area includes 15 percent of the U.S. population (48 million people). FoodNet is the principal foodborne disease component of CDC’s Emerging Infections Program (www.cdc.gov/foodnet/index.html).

Integrated Food Safety Centers of Excellence (CDC)

The Integrated Food Safety Centers of Excellence provide assistance and training to other state and local health departments to build their capacity to track and investigate foodborne disease. CDC named Colorado, Florida, Minnesota, New York, Oregon, and Tennessee state health departments and their partner academic institutions as Centers of Excellence under the authority of the Food Safety Modernization Act (www.cdc.gov/foodsafety/centers/index.html).

Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (CDC)

All state health departments and several cities receive funding through this program. The cooperative agreement’s goals are:

- Building and maintaining an effective public health workforce for rapid response to infectious disease outbreaks
- Strengthening national surveillance systems
- Modernizing public health laboratory capacity
- Improving health information systems to efficiently transmit, receive, and analyze infectious disease-related data electronically

(www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html)

OutbreakNet Enhanced (CDC)

OutbreakNet Enhanced helps state and local health departments improve their capacity to detect, investigate, control, and respond to enteric disease outbreaks. Currently, 26 states and three large cities participate in the program. The network of epidemiologists supported by OutbreakNet Enhanced helps sites better prepare for and respond to outbreaks (www.cdc.gov/foodsafety/outbreaknetenhanced/index.html).

FoodCORE (CDC)

FoodCORE funds 10 state and local health departments to develop new and better methods to detect, investigate, and control outbreaks of foodborne diseases. In 2017, the FoodCORE centers published a success story about their experiences adapting to culture-independent diagnostic tests and a model practice on strategies for improving team communication and collaboration (www.cdc.gov/foodcore/index.html).

indicated that these samples were highly related to the clinical cases. The four samples were collected from a bread rack dolly, a swinging door, and two different floor mats. It was recommended that Establishment D hire a consultant, replace the old floor mats, and clean and sanitize the entire facility. They were forbidden from serving ready-to-eat foods until cleaning and sanitizing was completed and repeat environmental sampling indicated *L. monocytogenes* was no longer present in the facility.

The use of WGS and collaborative environmental sampling by different agencies to solve *L. monocytogenes* outbreaks is a proven success story. Epidemiology, environmental health, or laboratory services individually cannot solve an outbreak. The three-legged stool approach combining epidemiological information collected from patients, environmental health information collected from establishments, and WGS results from the laboratory allow us to detect more clusters of illness, link more cases to a likely source, identify unrecognized sources of illness, and stop outbreaks before they escalate in size and severity.

Conclusions

These three foodborne illness outbreak investigations exemplify the dedicated professionals working throughout the United States. Their efforts result in reducing the number of potential illnesses and finding root causes that can assist in prevention of similar illnesses in the future. While typically behind the scenes, professionals managing the outbreaks at state and local health departments are often the unsung heroes of public health. ■

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By Carol Wallace, Ph.D., Neil Bogart, Mike Bartikoski, M.B.A., and John Butts, Ph.D.

Food Safety = Culture Science + Social Science + Food Science

Practices for moving beyond compliance to commitment

Food safety culture works at the intersection of food science, organizational culture, and social cognitive science.[1] We need to understand the interactions between traditional food sciences, including food safety, and the sociocultural sciences to determine what food safety culture is and how it can be measured and improved. Although everybody is talking about it, food safety culture is a relatively new concept for the food industry, and it is useful to look back at food safety assurance developments in recent history to understand our route into food safety culture and why it is so important today. In this article, we will consider how thinking in food safety culture has developed and how blending the food and sociocultural sciences together helps us improve food safety performance.

The Path to Food Safety Culture

Starting with food safety management systems and, in particular, Hazard Analysis and Critical Control Points (HACCP), most people will know very well the history of HACCP through the U.S.-manned space program and the work of the Pillsbury Company.[2] Integrating failure mode effects analysis (FMEA), which has been used since World War I, this pioneering work in the 1960s and '70s laid the foundations for food safety systems and practices that still form the mainstay of food safety management today. Thirty years ago, a new graduate entering food manufacturing would have been lucky to get involved in early HACCP if they worked for one of the early adopting companies. Remember, this was before publication of the

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HACCP principles by Codex and the National Advisory Committee on Microbiological Criteria for Foods,[3,4] and it was through these texts and some early regulatory standards that HACCP really started to take off in the 1990s. Early on, HACCP was reported by the World Health Organization (WHO)[5] as an effective and economical way to prevent foodborne disease; this was a widely shared view that led some governments to believe that its implementation was a remedy for all food safety issues.[6] In some markets, HACCP was microbiology and compliance driven, while others recognized its role in continuous improvement and doing the right thing.

Through the 1990s, there was much focus on HACCP training and the development of formal HACCP plans, with the later understanding of the importance of also formalizing the supporting prerequisite programs to control the general operational hygiene conditions. However, foodborne illness outbreaks continued to occur, and auditors of HACCP systems started to see problems with both the design of HACCP plans and their implementation.

HACCP was, and is, a logical approach to food safety control. By identifying the hazards that could occur and potentially make consumers ill, appropriate control measures could be designed and implemented. While great in theory, this was not working well in practice; steps needed to be taken to ensure that systems were working effectively.[7] What was missing was the social science side and an understanding of the crucial role of people from a scientific perspective.

Some aspects of people systems, such as knowledge and training, have long been associated with food safety management systems (FSMSs) and HACCP in particular;[3,6,8–10] these are also items that have been identified as barriers to successful food safety management.[11] Also identified as important in early HACCP guidance was management commitment,[3,4,8] which was thought to come from an understanding of the potential impacts of unsafe food on the consumer and the business: In other words, senior managers seeing food safety management as the right thing to do. HACCP awareness training was often suggested for senior managers and the workforce in general to help share this understanding and commitment throughout food companies, and the demonstration of commitment by managers was seen as important for workforce commitment and behavior. These early clues to the impact of people and culture on effective FSMSs have evolved into the considerations of organizational and food safety culture today.

Even though the U.S. has started implementing the Food Safety Modernization Act (FSMA; signed into law in January 2011) and numerous other countries have updated their food safety systems, we continue to have increasing numbers of major foodborne illness outbreaks. According to the WHO, there are about 420,000 deaths a year from foodborne disease and about one-quarter of those deaths (~125,000) are children under 5 years old.[12]

Some key questions on the table are: Do HACCP-based FSMSs (HACCP-FSMSs) still work? Is the problem with the core principle of our HACCP-FSMS? Or is our food safety culture not truly developed? We propose that HACCP-FSMSs work, but our food safety culture is currently in disarray. We need to be working together to deliver safe food 24/7, and we need measurement systems to understand the maturity and effectiveness of the food science and culture elements.

Some Symptoms of a Food Safety Culture in Disarray

Food hazards and business risks

While we might have good systems to identify, assess, and control food safety hazards through HACCP, we need to recognize that our systems might not work if our food safety culture is poor. We also must recognize business risks where procedures are not effectively understood, honored, or enforced. Economic adulteration is a good example where food safety may not initially appear to be an issue, but the melamine incident[13,14] proved otherwise. Another business risk example relates to the arbitrary extension of shelf life of frozen meat to prevent financial loss. Food safety science may not have had a problem with extending the code life, but customers receiving the finished product and the consuming public reacted differently. Through not understanding the potential consequences, the loss for both the manufacturer and its customers was extreme. These two examples have their roots in culture. The foundation of a company's food safety culture is defined in corporate values, but other factors such as customs of a population may play a role in employee actions. Managers must recognize the scope of actions that can create a food safety hazard and business risk.

Quality department is the policing department

In the two prior examples, loss of life and loss of business were the consequences of failing to have science and values effectively deployed. These are extreme examples, but each recall, withdrawal, and food safety-based embargo represents a failure to effectively deploy the necessary process to prevent. Does our organizational culture promote prevention? Do programs and projects reflect an understanding of our values? Our goal in manufacturing is to create habits within our employees based on doing the right thing. This applies to every production worker and management associate or team member rather than just food safety and quality. When correct actions are performed without thinking, then the culture has reached a new level of maturity.

Settling for executing programs at the existing level – Compliance vs. continuous improvement

The development of preventive practices designed to address defined hazards and reduce business risk is primarily led by the food safety department. Some misguided management priorities that we have encountered include team members not having time to work on a project that will significantly improve food safety as well as provide data to reduce risk because they are too busy preparing next month's customer

or third-party audit. In the absence of effective or strong leadership, managers often tend to stay in their comfort zone and work to set requirements rather than making continuous improvements.

Food safety measurements based on prevention and prediction vs. verification of the effects of the loss of control are simply not practiced enough. Most environmental monitoring programs by design are only verification driven. Verification positives mean we have lost control of the process and food safety issues can arise. Finding indicators of the potential loss of control vs. finding a zone 2 or 3 verification site, contact surface, or product positive should produce different reactions. We must recognize risk and measure the critical factors and indicators of process control for continuous improvement.

Lack of personnel and cross-functional team involvement

Let's take a 20,000-foot view of communication systems in plants. Daily production and quality paperwork are generated by operations and food safety and quality. The information moves upward in the organization in the form of various reports. Some results are shared with the workforce along with problems encountered. The workforce often gets the opportunity in some form to reinspect, recondition, or rework product that management doesn't want to ship. This downward-only communication chain can make individuals feel like mushrooms: "Keep me in the dark and feed me manure." This may be an extreme example, but the most common employee complaint is the lack of communication.

Often missing is an open transparent discussion between leaders and employees about what's most important to individuals and their companies. This will lead to conversations about competing priorities and different expectations. On the team side, many of the program maintenance issues raised in audits today can be addressed easily and quickly by cross-functional teamwork. The problem is that we don't do enough of it, so we are losing the chance to enhance employee engagement and buy-in while driving involvement through the organization. These management actions help define accountability as well as enhance food safety culture.

Imbalance between use of positive and negative consequences

In many food companies, plant managers are recognized for their ability to make quick decisions and create drive to get it done. Food safety management's role is to deploy science to help plant management promote safe food production through the organizational culture, values, and norms.

The successful use of consequences helps in continuous improvement of food

safety culture. The outcomes of our measurement systems need to create more positive reactions than negative. Overwhelming negative consequences drive negative reactions and a disengaged workforce.

Issues with food safety skills and technical training

Would you knowingly allow a surgeon to operate on you or your family when the surgeon has had only 18 hours of training to be a surgeon? We rely on individuals in the food industry with as little as 18 hours of training on HACCP to develop our FSMSs. Even with new FSMA training requirements, only 18–20 hours of training are needed to get your Preventive Controls Qualified Individual certificate required for every manufacturing facility selling into the U.S. or manufacturing goods sold in the U.S. Are 18 hours enough?

Some of us get calls asking if we know of someone who can step into a company's open food safety and quality manager position, but often the company wants to spend only a certain figure for their FSMS expert that would attract a graduating food science college student. Often the response to such an inquiry is "students don't know enough," but rather than increasing the salary budget, companies will promote someone from inside, frequently with no formal food safety education or training, into the position. Then, these new hires are sent off for the 18-hour HACCP course and are suddenly the company's food safety expert. On the other hand, the lack of appropriately trained graduates is a real and significant problem, partly because food science curricula often don't include enough food safety science or social science content, and partly because students see other work areas, such as product development, as more exciting career paths.

We can have the best knowledge at the corporate office, but if we do not have effective, robust, and continually improved training programs, we will not succeed. These problems occur in both small and large companies. The small company may not be able to afford to train employees, even though one issue could shut them down permanently, and the large companies can afford the food safety professionals, but sometimes the information is kept at corporate and not disseminated down throughout the processing facilities.

Making Science-Based Improvements

Use the social science toolbox to bring your food safety culture back on track

Acknowledging that we have challenges with connecting the proven principles of food safety management such as effective and dynamic HACCP programs, what can we do? We suggest four areas (Figure 1) from the social science toolbox that have worked in our experience to improve food safety performance and continually improve the food safety culture.

Figure 1. Some tools from social and organizational sciences to help you in your work to improve food safety performance.

Drive food safety through company and personal commitment

Science and values define the right thing to do. Our friend Dave Theno carried a picture of Lauren Rudolph, who died at age 6 from the 1993 Jack in the Box outbreak, in his briefcase. He would pull it out and ask, "What would she want me to do?" when faced with a significant food safety decision. This made the value of the decision real and helped guide him to his decision. Does each of our company values enable us to put a human face on our decisions? When we educate or train, do we make it real and explain "why"? Do we use or engage the company values when we make decisions? Are the effects and potential impacts of our programs evaluated against our company values?

Does company management, including food safety management, realize how to drive the company and food safety culture away from firefighting and into a preventive and predictive state? Can the effects of those preventive and predictive practices be internalized and become a key component of the overall business strategy? The consideration of these questions when establishing food safety goals is essential for continually improving your food safety culture.

Our programs and procedures must be in concert with company values. We must interpret and deploy values on a daily basis and show through our actions that they are what we stand for. Leadership is leading by doing and "walking the talk." Food safety leaders must expect value-driven actions and accountability. These words make a lot of sense on paper, but how often have you held your supervisor or boss accountable or challenged them regarding a decision, procedure, or activity that had food safety implications? Our ability to hold those above, below, and equal to us accountable for food-safe actions and decisions is key to driving the appropriate food safety culture.

As food safety leaders, our management obligation is to use those values at all levels in the organization to drive food safety culture.

Workforce engagement

Engaging the workforce in teams promotes our ability to increase ac-

countability and responsibility. Engagement through tools such as brainstorming, cause-and-effect diagrams, and root-cause analysis helps create and allows us to understand preventive controls. Diligent use of such tools leads to the capability for more advanced tools such as FMEA and/or other options from the lean-manufacturing toolbox. Effective use of teams and teamwork helps move the organizational knowledge to the front line while enabling cross-functional communication and sharing of ownership of change.

Communication tools are a major part of improving engagement. Food safety engagement in daily team huddles as well as longer sessions (e.g., weekly team meetings) is critical. Food safety metrics along with human health and safety must be top agenda items in these communication activities. Food safety and quality must ensure the communication includes recognition of project work to improve quality and productivity as well as food safety. Use of these tools to close the communication loop is an essential component of improving food safety culture. This approach also addresses the need for better communication and provides employees with channels for more direct dialogue on critical issues. This increases the employees' sense of impact on the job, which drives engagement.

Figure 2. The 4E's Model of Behavior Change

Practice and success demonstrates that two fundamental changes are required of us as food safety leaders at all levels to attain results through engagement:

1. We must abandon the view that we are or should be the sources of all solutions in the food safety space and truly open up to the reality that inclusion of broader teams leads to more and better ideas and solutions. Therefore, we need to evolve from direct knowledge holders to coaches and facilitators who steer cross-functional group actions from our informed food safety perspective, developing real understanding in our teams closer to the issues through the use of, for example, huddles and gemba walks, to find out and address what is really happening.
2. We must ensure that the emphasis shifts away from cost in the short term to the improvement of process and other variables that focus on making the attainment of the finished goal easier for the teams–eliminating steps, changing methods, changing layouts, and giving more control at the point of decision and adjustment,

within the framework of food safety. Eventually, costs and value will be improved. Leaders who put people first, ensure their teams know what is expected, and give the teams the tools to attain those expectations will have greater success than those that put cost first.

The difference is in how management sees itself–as the sole creator of solutions or as a coach, facilitator, and conduit for the teams to actively transform how they do their jobs each day, which ultimately improves their value delivery (and engagement) at work.

When these systems reinforce company values, alignment to corporate strategic plans and initiatives can be realized. Food companies with a high food safety maturity level have a preventive mindset, and accountabilities and responsibilities are aligned for everyone. Employees feel empowered and understand why food safety procedures must be practiced. When an employee in a highly mature company enters the factory, their commitment is consistent with the company's values and results follow.

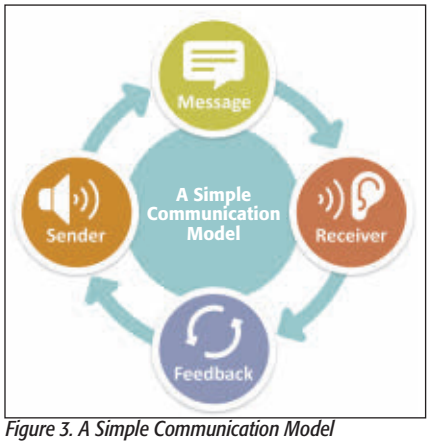


Figure 3. A Simple Communication Model

Make food safety a habit

Social science teaches us how to turn instructive actions into habits without thinking. Habitual actions toward situations must become acceptable norms within the various work groups in the plant and company. "Acceptable norms" mean the leaders of these various work groups accept and expect these actions in response to the situation. Think of street gang activity and their ability to establish acceptable norms. Take your memory back to high school and the cliques that autonomously formed. Street gangs and high school cliques create value-driven reactions to situations. The effects on new members initially change beliefs then create habits. How do we, without imposing gang activity, address the work groups to recognize, accept, and react in a food-safe manner?

Behavioral change tools from social science can help with this, such as those from the 4E's model,[15,16] which considers the systems and capacity to enable change, working with trusted intermediaries and networks to engage change, the shared responsibility needed to exemplify change, and the need for incentives and disincentives to encourage change.

Figure 2 shows that we need to: **Enable**, making it easier by providing people with the support they need to make the right choices; **Engage**, getting people involved early on so that they understand what they need to do and helping them develop a sense of personal responsibility, developing new "social norms"; **Exemplify**, leading by example in line with company values and policies; and **Encourage**, giving the right signals, reaffirming benefits of change, and providing regular feedback. Looking at all 4E's, we need to consider whether the overall package of interventions is enough to catalyze change; it is important to review this on a regular basis as progress is made.

Transparency and communication

Scientific, technical, and societal elements are different today from what they were 10–20 years ago. Twenty years ago, social media did not exist as it does today. Transparency was not a norm. "What you don't know won't hurt you" was more the norm. Today, we all operate in glass houses. Every action and reaction has some level of visibility. Our current state of communication technology has enabled cellphone pictures and videos to touch thousands in just minutes. Getting the culture right is one way of protecting business in this arena.

When you ask, "What can we as a company do better," the very common response is, "Provide more communication." As usual, the devil is in the details–understanding what sort of additional communication is needed along with what the receivers expect and interpret from the communication is crucial (Figure 3). The truth is that most companies that increase the number and frequency of communications don't move the needle–it isn't about *more* communication, it is about *better* communication–and to make communications better, we need a fundamental understanding of how the communication process works, what folks expect and need from communications, and how that differs from what they are getting. Without that understanding, many attempts to improve communications will fail.

Figure 3 shows the communication cycle in its simplest form, but we need to remember that the receiver has to decode the message to his/her own understanding,[17] and this might be affected by the chosen communication channel, for example, email, telephone, in-person briefing, etc., and by nonverbal signals. In other words, the chosen communication channel can add "noise" that interferes with the intended message being understood.

Our current methods for sourcing feedback–annual engagement surveys and survey technologies like SurveyMonkey®–often take too long and as a result of the design, build, deploy, analyze, and report-out cycles required of our current feedback processes. Leaders are too slow to take action–it takes 3–6 months on average to move from data collection to action planning on a typical annual employee survey. Many companies don't even get to developing action plans, which erodes organizational trust. The bad news is that our organizational feedback processes are entrenched by habit and woven into the fabric of core business processes. It takes a progressive and forward-looking leader to spot this trend–you have to be courageous to try something new!

The risk to companies that don't adapt to real-time feedback trend is great. After all, in the modern knowledge economy, employee engagement is the capital that keeps the economic engine running. If we don't know how our employees feel today, we need to find out and ask them what they think. We need to respect them for their unique perspectives and experiences. In this way, employees feel connected emotionally to the purpose of their organizations and know how their contributions are driving their businesses forward. We can't foster this type of culture just by checking in once or twice per year.

How to blend the food and social sciences together for food safety effectiveness

The ease of implementing new food safety programs is directly proportional to the maturity level of the food safety culture. Is the ease of implementing new food safety programs then a measure of food safety culture? The elements affecting ease of implementation include trust, engagement, buy-in, intention, belief, understanding, and behavior. We have discussed these issues and some of the questions in the thought process of those who are tasked with implementing, complying with, and maintaining changes. People ask "Is this the right thing for me, for my department, for the company?" "Will this make my job easier or harder?" "Are we capable of accomplishing and complying?" "Is this really going to be sustainable?" Addressing these questions as part of the implementation process helps address the culture or social science side of the proposed change.

To implement effective change, we must blend practical knowledge from organizational culture science, social sciences, and food safety science. For example, a company value reads, "The customer always come comes first." Senior leaders act on this value by holding sales accountable for engaging key customers to brainstorm new product ideas or improvements to existing products. Sales knows how to assess food safety hazards and ensures that representatives from both customer and company food safety are involved in the brainstorm. A new product is developed, and the product development team assesses hazards and physically conducts brainstorming sessions at the production site with involvement from the leadership team to frontline employees and, together, they proactively identify hazards and risks when producing the product. As this example shows, there are two prevailing change management principles at play: planning and involvement. We all go through the same emotional spectrum when experiencing change that is important to us, and, as leaders of change, it is our responsibility to use the known principles of social science to make the "pain" of change be short and controlled.

(continued on page 66)

By Rodney A. Moxley, D.V.M., Ph.D.

Progress in STEC Control: The USDA-NIFA STEC Coordinated Agricultural Project

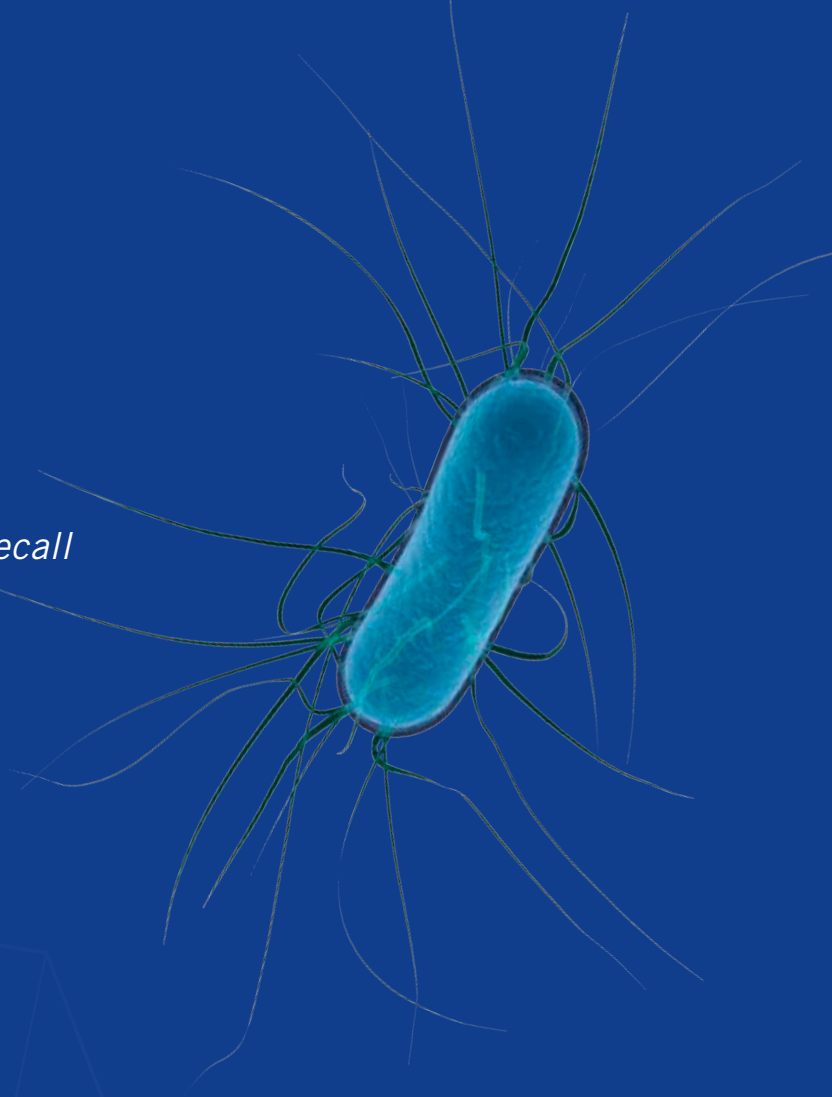
STEC program spreads awareness of public health risk and remedies

Shiga toxin-producing *Escherichia coli* (STEC) strains pose a major threat to public health. STEC causes an estimated 265,000 or more cases of illness in the U.S. each year. In addition to the consequences of illness, including loss of life, these cases result in annual losses of about $500 million to the U.S. economy. Cattle are a major reservoir of STEC: Bacteria colonize the intestinal tracts and are shed in the feces. Consequently, STEC infections also result from direct contact with cattle, contamination of other sources of food (e.g., fresh produce), and other means. Worldwide, approximately half of all STEC cases are attributable to foodborne exposure, whereas about half of foodborne cases are attributable to beef. Globally, beef is the leading food source for STEC infection.

To respond to these issues regarding STEC in beef, the U.S. Department of Agriculture-National Institute of Food and Agriculture (USDA-NIFA) funded a proposal by the University of Nebraska–Lincoln (UNL) and collaborating institutions to develop a comprehensive research, education, and extension program. This program, known as the STEC Coordinated Agricultural Project (STEC CAP), has been funded by an award of approximately $25 million from USDA-NIFA. The project began January 1, 2012, and will end December 31, 2019.

The STEC CAP has worked to strategically conduct research and educate communities on how STEC contamination and outbreaks occur and spread throughout the beef production/processing chain, and on how science and technology can best be used to mitigate risks. The STEC CAP, with me at UNL as project director, has included 53 scientists and educators at 18 institutions: UNL, Kansas State University (KSU),

Only one cell could cause a recall



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USDA Agricultural Research Service (ARS; Eastern Regional Research Center and Roman L. Hruska U.S. Meat Animal Research Center), Virginia Polytechnic Institute and State University, University of Georgia, North Carolina State University, University of California–Davis, University of Delaware, New Mexico Consortium (Los Alamos National Laboratory), New Mexico State University, University of New Mexico, Texas A&M University, University of Tennessee, Mississippi State University, University of Maryland Eastern Shore, West Texas A&M University, Alabama A&M University, and Souderton (Pennsylvania) High School.

Project Goals and Objectives

The overall goal of the STEC CAP is to reduce the occurrence and public health risks from seven serogroups of STEC (O157 and six non-O157) regulated in beef by the USDA Food Safety and Inspection Service using a quantitative microbial risk assessment (QMRA) platform while preserving an economically viable and sustainable beef industry. In addition to this overall goal, the project's five objectives, focusing on STEC in beef, address: 1) detection, 2) biology, 3) intervention, 4) risk analysis and assessment, and 5) risk management and communication. The grant has yielded many significant outcomes and impacts, as documented, in part, by numerous refereed journal articles and other important activities and outputs.

"Shiga toxin-producing *Escherichia coli* (STEC) strains pose a major threat to public health."

Objective 1

In addressing Objective 1, reagents and methods for detection and quantification of STEC in the beef chain were developed or improved. Many commercial antisera to non-O157 and O157 STEC lacked specificity, limiting their usefulness and indicating the need for better reagents. Consequently, monoclonal antibodies against non-O157 antigens (O26, O45, O103, O104, O111, O121, and O145) were developed. These antibodies are currently undergoing comprehensive specificity testing. Enrichment broth and agar media for detection of non-O157 STEC were evaluated, and improvements in the sensitivity and specificity were made through adjustments in the concentrations of antimicrobial selective agents. A spiral-plating method for quantification of non-O157 STEC was developed and validated. Conventional and real-time multiplex polymerase chain reaction assays for non-O157 and O157 STEC detection and quantification were developed and validated. A novel waveguide-based optical biosensor for the detection of *E. coli* lipopolysaccharide and Shiga toxin was developed and validated. The development and optimization of reagents and methods of detection and quantification have improved food safety by enhancing the removal of these organisms or contaminated products across the beef chain.

Objective 2

In addressing Objective 2, epidemiological studies conducted under the STEC CAP generated data for the QMRA and identified factors that influence the prevalence and concentration of non-O157 and O157 STEC organisms in cattle, their environments, and on hides and carcass surfaces. Season, region of origin, and the interaction of these factors were found to affect hide contamination of market beef cattle at slaughter by STEC, and each serogroup responded uniquely to these factors. Hides were the major source of microbial contamination in beef processing plants; however, hide contamination with some major STEC serogroups differed significantly among cattle types at harvest even within the same day and location.

E. coli of the targeted eight serogroups, but not STEC, was detected in houseflies from an urban environment. Detection of *E. coli* of the targeted serogroups with the potential to acquire virulence factors indicates that houseflies in an urban environment represent a public health risk. Other experimental studies found that houseflies could potentially serve as vectors for non-O157 STEC.

The concentration and molecular characterization of O157 and non-O157 STEC isolates from rectoanal mucosal swabs of feedlot cattle over time was determined. In addition to O157, non-O157 STEC were transiently present at high concentrations in the rectoanal mucosal region of cattle. Modeling of pen-level fecal prevalence data from feedlot cattle found that O157 but not non-O157 STEC had the potential of persistence in a population. Microbiome studies on feedlot cattle determined that lower levels of hide bacterial diversity corresponded with non-O157 and O157 STEC contamination, and the presence of certain bacterial populations typically associated with soil occurred in the absence of these STEC populations. Other studies determined that cattle do not harbor the highly virulent STEC serotype O104:H4, which, although not regulated in beef by the USDA, caused a large outbreak in Europe in 2011. This answered a key question as to whether cattle or foods derived from them constituted a source or risk for this particular pathogen.

STEC isolates from studies have undergone microarray analysis, whole-genome sequencing, and analysis of virulence gene content, generating information that has increased our understanding of the risks they pose. A serotype of STEC known to cause sporadic cases of hemorrhagic colitis and hemolytic uremic syndrome in human patients (O165:H25) naturally caused clinical illness manifested as hemorrhagic colitis in feedlot cattle as old as 1 year of age. This was the first report of disease in cattle associated with STEC O165:H25, the oldest bovine STEC disease case with isolation of the pathogen, and the first bovine case to demonstrate

grossly evident, hemorrhagic, colonic mucosal erosions associated with enterohemorrhagic *E. coli* infection.

A study estimating the prevalence and concentration of regulated STEC in retail ground veal, veal cutlets, and retail ground beef was completed. Bacterial concentration (mesophilic aerobic plate count, total psychrophilic aerobic plate count, and Enterobacteriaceae) in spent marinades from specialty retailers was significantly affected by the marination method. In general, bacterial concentrations were higher in marinades used for tumbling. These findings underscore the importance of maintaining marinade solutions and meat at a safe temperature (≤ 4 °C). They also emphasize the importance of frequent sanitization of the equipment and environment in the processing area and deli case.

Objective 3

In addressing Objective 3, multiple interventions to control non-O157 STEC at different steps of beef processing in plants were validated. Through these modifications, for example, the use of electrostatic spray or sprayed lethality in container methods, antimicrobial agents had increased efficacy through more uniform contact with target surfaces yet reduced cost through reduced water usage. Data collected from packing plants helped identify processing steps where water recycling and reduction were needed. Viscera processing generated the largest wastewater load; hence, any improvements in this process would positively affect the sustainability of cattle slaughterhouses. Changes made to reduce water usage could pay for enhanced antimicrobial intervention in the plant. Interventions effective for STEC O157:H7 on nonintact beef were equally effective against the regulated types of non-O157 STEC. This information appreciably reduced the nature and scope of additional scientific studies needed for mitigation of the risk of STEC in beef and obviated the need to modify existing processing technologies or develop additional interventions specific for the regulated non-O157 STEC.

An innovative framework to systematically estimate and compare disease burden associated with U.S. beef consumption (i.e., foodborne risks) and U.S. beef slaughtering/processing (i.e., environmental and occupational risks) on a common metric, disability-adjusted life year, was developed. Although uncertainties and underestimation might exist in this study, results showed that environmental and occupational risks at beef slaughtering/processing are of the same magnitude as foodborne risks of beef consumption. By disclosing the relative magnitude of the three risks associated with U.S. beef consumption and slaughtering/processing, this work can help decision makers target efforts on minimizing the overall human health impacts of the U.S. beef industry and has broad implications for other food processing industries.

Studies were conducted that focused on STEC translocation and end-point cook-

ing temperatures on mechanically tenderized nonintact steaks to fill key data gaps for determining risk of blade-tenderized and brine-injected steaks compared with nontenderized beef. Federal regulatory agencies used data to update risk assessments and support rules for labeling beef products that have been tenderized and, therefore, rendered nonintact. Through this, guidance was given to Canadian authorities for similar labeling and rule-making initiatives. The veal industry was provided with scientifically validated and USDA-approved antimicrobial carcass interventions for application as part of an effective veal slaughter Hazard Analysis and Critical Control Points program to control STEC with no adverse effects.

"The STEC CAP has had major, cross-functional impacts on beef safety research and education, with positive public health implications continuing for years to come."

STEC CAP research showed the role of economic incentives in adopting tools and technologies to improve food safety. Consumers are, to some degree, averse to many new technologies and approaches to reduce the risk of human illness from pathogens. However, consumers are also willing to pay a premium for a product (e.g., ground beef) in which preharvest interventions have been used and contain a food safety label with an informative message. A study examined the impact of information about food irradiation on consumers' willingness to purchase irradiated ground beef and poultry. A combination of messages, including that irradiation effectively reduces harmful bacteria, is safe, and does not significantly reduce the nutritional value of the food, was the most effective in increasing interest in irradiated food. Policy makers, educators, and marketers could use this information to accurately describe irradiated food products and increase their use by consumers.

Several other consumer research studies were conducted to improve food safety. The food-handling practices of television celebrity chefs and consumers' and culinary students' attitudes toward mishandling were studied. Video clips of programs were shown to culinary students to assess their attitudes toward chefs as role models and to consumers in focus groups to measure attitudes toward chef practices and the influence of these attitudes on personal behavior. Culinary students believed chefs should serve as positive role models for consumers. Some consumers were unaware of the chefs' breaches of food safety and admitted they had used similar practices. The findings indicated that consumers viewed celebrity chefs as role models, utilized information transmitted during cooking shows, and often practiced the behaviors they observed.

Food safety education for people with diabetes or pregnant women using a positive deviance (PD) model was developed. The PD focus group is a novel educational intervention that allows participants to discuss their food-handling behaviors and decide to try recommended positive practices modeled by people like themselves. Results indicated that PD discussion modules could be promising alternatives to traditional methods of food safety education. Compared with those who merely read educational information, participants in a PD intervention had higher knowledge scores and adopted more safe-handling recommendations. This suggests that food safety education is most effective when delivered in a supportive discussion format. Health education programs for these vulnerable groups should endeavor to deliver safe food-handling guidelines through a PD approach.

A study explored actual risk-communication behaviors of restaurant servers. Secret shoppers visited 265 restaurants in seven geographic locations across the United States, ordered medium-rare burgers, and collected and coded risk information from chain and independent restaurant menus and from server responses. The majority of servers reported an unreliable method of doneness (77%) or other incorrect information (66%) related to burger doneness and safety. These results indicated that major gaps in server knowledge and risk communication exist. The study also indicates that food establishment staff need to be adequately trained and should provide consumer-advisory messages that are accurate, audience appropriate, and delivered in a professional manner so that customers can make informed food safety decisions.

Recipes containing raw animal ingredients in 29 popular cookbooks were evaluated through content analysis for messages related to safe end-point temperature recommendations and reducing cross-contamination risks. Of nearly 1,500 cookbook recipes containing a raw animal ingredient, only 8.2 percent included an end-point temperature, and only 72.3 percent of these gave a correct temperature. Neutral and positive food safety behavior messages were provided in just 7.2 percent and 5.1 percent, respectively. The lack of correct food safety guidance in cookbooks may increase the potential for risk of foodborne illness, and popular cookbooks are an underutilized avenue for communicating safe food-handling practices.

Objective 4

In addressing Objective 4, a working computer model of the QMRA for STEC was developed. The QMRA model estimates the risk associated with each regulated STEC serogroup to provide a basis for decision making and optimal risk management. In addition, it estimates the value of intervention in decreasing the risk of product contamination and human disease, including the sensitivity of the system to control components. The QMRA model will allow both policy makers and beef processors to develop operating procedures that reduce risk and improve food safety.

Objective 5

In addressing Objective 5, bilingual (English and Spanish) online training modules on pre- and postharvest STEC prevention in beef and veal were developed and made publicly available.[1] The modules, intended for employees in agriculture and the foodservice industry, can electronically track training. Other STEC topic-based educational modules were developed and made available as upper-level undergraduate and graduate distance-education courses at several universities. Extension personnel produced an instructional video entitled E. coli *Sampling for Beef Carcasses* for use by plant employees[2] and hosted several workshops. Another project documented the impact of more effective ways of delivering safe-handling education and PD intervention as an alternative to traditional methods of food safety education for people at an increased risk for foodborne illness. Educators and their teams partnered with over 70 food science club students at five participating universities and trained them in engaging with tailgaters, collecting data, and answering questions related to beef safety. Social media effectively reached the public with food safety messages including STEC. A social media website has 71,000 subscribers and 13,813 archives.[3] A food safety message for the public that stresses cooking burgers to 160 °F was created and is available as an animated video.[4] This was shared on theater screens and as radio ads and Pandora announcements in Fayetteville, North Carolina.

Multiple Approaches to Educating the Public

Risk reduction through education has occurred through several other modalities. The website for STEC CAP (www.stecbeefsafety.org) has been maintained and updated throughout the project and continues to deliver STEC risk and other related information to the public. Fifty-five graduate degrees (30 M.Sc. and 25 Ph.D. degrees) have been completed through STEC CAP-funded assistantships and projects. Thesis- and dissertation-driven research yielded many of the aforementioned journal publications and prepared these graduates for careers in food safety and related fields. Further, 103 interns, primarily undergraduates, completed research or education projects that addressed STEC CAP objectives, and 429 externships gave students, mainly high schoolers, one-day exposures to food safety research and education. Seven secondary education teacher workshops led to the development of new curricula approved by both the Nebraska and Kansas Departments of Education. The curricula are a series of courses taught in over 100 middle and high schools in Nebraska and Kansas[5] and involve inquiry-based learning with information on *(continued on page 66)*

By Larry Keener, CFS, PCQI, and Geoffrey Smithers, Ph.D.

Whey Powder and Food Safety Risks: A Lesson in Validation and Verification

In July 2018, a number of well-known retail snack products in the U.S. market were recalled because they all contained a common ingredient–whey powder–and there was a possibility that one or more batches of the whey powder used in these products were contaminated with *Salmonella* bacteria.[1] This possibility created an unacceptable food safety risk for manufacturers of the snack products and they were thus recalled. Thankfully, no illnesses (or worse) have been reported in relation to these recalled products. While the outcome for consumers in this recent "scare" was good, and the regulatory and oversight regimes appear to have worked effectively, the manufacturers, both of the whey powder ingredient and the retail snack products, have suffered both economically and in terms of their reputations.

Taking a close look at the recent whey protein powder recall

This recent food safety event highlights the critical importance of ongoing diligence in better understanding the likely sources of food safety risks and, following their identification, of taking suitable action to minimize these risks. In terms of whey powder, and other whey-based ingredients for that matter, understanding the ingredient and how it's manufactured are important steps in identifying potential points of food safety risk, and thereby the best strategies to analyze for and minimize the risk.

In this article, we provide an overview of whey and whey powder, including the raw material, processing methods used in production, potential hazard points for food safety risk, strategies to minimize the risk, and modern validation, verification, and regulatory developments for food safety oversight.

Whey and Whey Powder Production

What is dairy whey?

Cheese, casein, and Greek yogurt production all lead to the generation of copious amounts of a dairy whey by-product.

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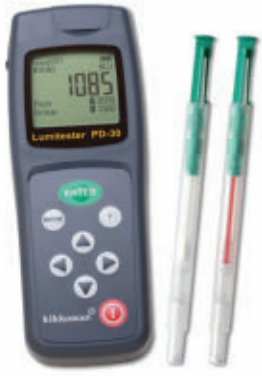

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For example, the production of 1 kg of some cheese varieties leads to the generation of up to 9 kg of whey. Nowadays, more than 200 million tons of whey are generated by the dairy industry globally each year, and this huge volume is increasing by about 2 percent annually. Historically, for the cheesemaker, this whey by-product represented a nuisance and the whey was therefore disposed of in the most economical manner, which often included spraying it onto fields, discharging it into rivers and oceans, and/or treatment by municipal sewage works.[2,3]

Cheese whey contains about 20 percent of the total milk protein and almost 100 percent of the lactose in milk, the latter in particular making this dairy by-product highly polluting (BOD > 35,000 ppm).[2,3] Changes in environmental protection legislation, together with a recognition of the value of various whey components, notably the proteins, over the past 50 years have catalyzed a reassessment of whey and its evolution from a waste by-product to a valuable raw material. Simple disposal of untreated whey has been outlawed in many Western countries, and industrial-scale manufacture of ingredients containing the various whey components has been made possible by technological advances in processing technologies, notably membrane technology and large-scale chromatography.[2,3]

Whey powder manufacture and food safety hazard points

While environmental protection and recognition of the functional and nutritional value of whey components drove the reassessment of whey as a dairy waste stream, the development of suitable cost-effective and industrially scalable processing technologies facilitated change. The ability to rapidly and economically process huge volumes of whey and at the same time to efficiently extract valuable components was a game changer. Nowadays, in most Western countries and many developing economies, very little whey is disposed of as waste. Rather, it is processed into a variety of value-added whey ingredients, isolates, and products. Figure 1[4] illustrates the various ingredients and products possible through the modern transformation of whey and the processing steps involved.

Simple dried whey powder is prepared by concentrating all the solutes in the separated and pasteurized whey stream (protein, lactose, minerals) using reverse osmosis and falling film evaporation, and then dehydrating the concentrate, usually using a spray drier (Figure 1[4]). The final dried powder contains approximately 75 percent lactose, 10 percent protein, 10 percent ash (minerals), and 4 percent moisture, and serves as an economical skim milk powder replacer in various food applications. The unit processes used to manufacture whey powder, while efficient and cost-effective, can create food safety hazard points if not maintained, operated, and cleaned correctly.

Ideally, the whey raw material should be separated and pasteurized, thereby providing a "clean" input stream to the reverse osmosis and evaporation plants. Incorrect pasteurization (e.g., not reach-

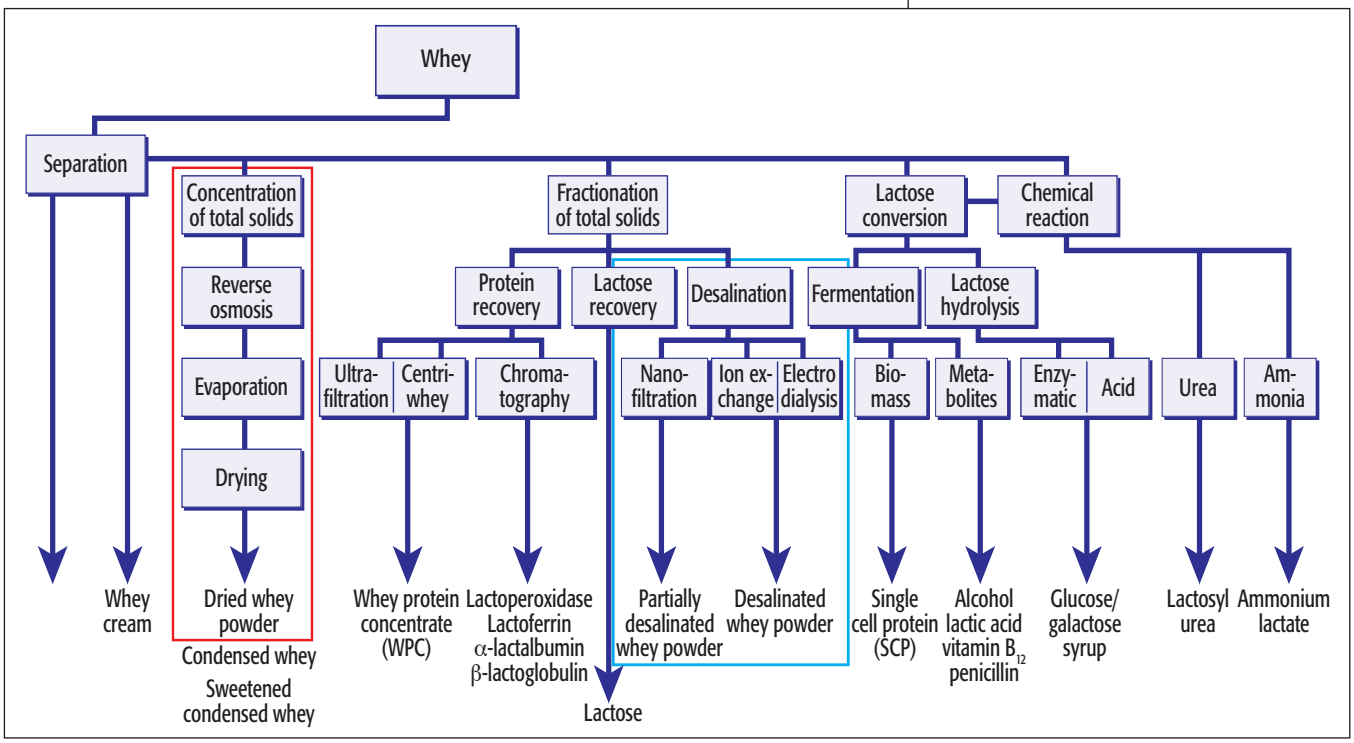

Figure 1. The fate of whey in a modern dairy-processing facility highlighting the various ingredients and products derived from the whey raw material and the processing steps involved in the transformation of the whey stream. The red box highlights the steps involved in concentrating and drying the whey into a simple powder. The blue box highlights more advanced processing involving demineralization of the whey prior to drying into demineralized whey powder.[4]

ing required temperature and/or hold time), for example, could lead to adverse microbiological and/or food safety problems downstream. The equipment must also be suitably maintained and regularly inspected. Effective cleaning and sanitation of dairy processing equipment remains an ongoing challenge. Ensuring all liquid contact surfaces in the equipment and associated pipework are exposed to the cleaning agents at the recommended concentration, temperature, and hold time will minimize any microbiological and/or food safety risks. In addition, achieving turbulent flow of the cleaning solution through the equipment, much of which has a number of moving parts, thin channels, and crevices, will maximize the cleaning result. If a complete clean is not achieved, bacteria can gain a foothold in these channels/crevices and "liquid dead points," potentially leading to bacterial outbreaks and biofilms that are difficult to remove.[5] Detection, evaluation, and control of these biofilms should be part of any modern food safety plan.[6]

The liquid contact material used in modern processing equipment is food-grade stainless steel, and while this material is durable and can be cleaned and made sanitary with suitable chemical agents (e.g., NaOH, hypochlorite), it is not inert. Acid and salt solutions (e.g., conditions found in some dairy whey streams and in cleaning agents) can cause pitting of the stainless steel over time and the pitted surface can become a haven for bacterial growth and create a challenge for cleaning. Regular inspection of the equipment is critical.

Membrane processing technologies, including reverse osmosis, nanofiltration, ultrafiltration, and microfiltration, have transformed the dairy industry over the past 50 years.[7] While these techniques have allowed for the processing of huge volumes of whey and the manufacture of valuable ingredients and products, including whey powder, they pose unique challenges in cleaning and sanitation. Many of the membranes used in dairy processing are organic in nature (e.g., polysulfone, polyethersulfone) and not chemically inert.[7] Thus, care must be taken when cleaning these membranes to ensure both sanitation and retention of functional performance. It's critical for the dairy processor to ensure cleanliness of the membranes, thereby minimizing any food safety risk associated with their use but also maximizing the functional life span of the membranes that represent a large capital investment. Strict adherence to the recommendations of both the membrane manufacturer and the cleaning agent supplier is critical.

A challenging technology to keep clean

Industrial-scale membrane processing of large volumes of dairy fluids, including whey, is usually undertaken in cross-flow configuration whereby the fluid being

processed is pumped under pressure across the surface of the membrane rather than directly through the membrane, the latter being very inefficient. To facilitate this cross-flow process, the membranes are usually constructed as spiral-wound modules with spacers and thin channels to maximize the available surface area in the module and to allow the pressurized fluid to flow across the membrane surface. These thin channels pose a particular challenge for cleaning and sanitation, and as such, it is important to ensure that all parts of the membrane module that come in contact with the fluid being processed are subsequently exposed to the cleaning agent under appropriate conditions (concentration, temperature, hold time, and turbulent flow where possible). Any "dead spots" in the membrane or the membrane plant that are not suitably cleaned will eventually lead to undesirable bacterial outbreaks and a potential food safety hazard. It is thus critical that regular inspections and testing are undertaken to ensure that the strictest cleaning and sanitation standards are being maintained.

Testing, Validation, and Verification, and Regulatory Developments

According to documents from the U.S. Food and Drug Administration (FDA), the suspect pasteurized sweet whey powder batches in the most recent scare were produced during four distinct periods that occurred between early May and mid-June 2018. The company that manufactured the suspect whey powder reported that results from their in-house pathogen testing program were negative for *Salmonella* but that retained lots of the identical powder subsequently tested positive for *Salmonella*.

"This recent food safety event highlights the critical importance of ongoing diligence in better understanding the likely sources of food safety risks…"

While simple, dried whey powder is a useful ingredient in a variety of formulated foods, the high ash/mineral content (~10% or higher) restricts its usefulness in foods where mineral content must be strictly controlled. Examples of the latter products include infant formula and various low-salt snacks, soups, dressings, and the like. To address the market demand for these products, demineralized (sometimes called desalinated or mineral-free) whey powders have been developed in which several techniques are used to remove (to a greater or lesser extent) the minerals from the whey prior to dehydration (Figure 1[4]). These processing technologies include ion exchange chromatography, electrodialysis, and nanofiltration.[4,8–15] Typical degrees of demineralization include 25–30 percent, 50 percent, and 90 percent, respectively. Industrial implementation of these demineralization technologies poses particular challenges when it comes to cleanliness and sanitation. Ion exchange chromatography, for example, is usually based upon the use of beaded substituted resins to remove the mineral ions from the whey stream. Modern resin beads are usually chemically robust but not inert and are also quite porous to maximize functional surface area. Therefore, strict adherence to the manufacturer's cleaning and sanitation recommendations (e.g., chemical agent, temperature, exposure time) will ensure safe operation and maximum functional life span.

Dehydration of the treated whey streams is an important processing step that renders the whey powder ingredient more shelf stable and also facilitates storage, transport, and distribution under ambient conditions (Figure 1[4]). At present, the most cost-effective approach to dehydration of large volumes of liquid is through the use of a spray dryer. In this process, the fluid to be dried is atomized into the top of a hot drying chamber, and the droplets of fluid are dried during their passage through the chamber.[16] The aim of drying is to render the product more stable at ambient temperatures, and this is usually achieved by reducing the moisture content to less than 5 percent and preferably to less than 4 percent. If for some reason a moisture content of less than 5 percent is not achieved, then xerophilic and/or osmophilic organisms (e.g., molds) may become a problem in the dried powder over time and as such may pose a food safety threat. Cleaning and sanitation of the spray dryer are critical steps in maintaining a safe processing environment. Modern spray dryers are designed to be cleaned in place. As such, there should be strict adherence to the recommendations of the equipment manufacturer and cleaning agent supplier for effective cleaning and sanitation, and the recommendations should be validated and verified.

Salmonella is an organism that can cause serious and sometimes fatal infections in toddlers and other small children, infirm or elderly people, and others with weakened and/or compromised immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream (sepsis) and producing more severe illnesses such as arterial infections, endocarditis, and arthritis. The primary mode of transmission typically involves a fecal-oral mechanism. This means that contaminated feces from an infected animal or person are somehow ingested by another person.

During the now-infamous Jewel Companies Inc. (Hillfarm Dairy) milk *Salmonella* outbreak in the spring of 1985, it was reported that approximately 170,000 people were affected. More than 16,000 cases were confirmed by laboratory analysis to be caused by the *Salmonella* Typhimurium strain of bacteria found as a contaminant in Jewel's dairy products. According to a study by public health scientists at the U.S. Cen-

ters for Disease Control and Prevention (CDC) and the Illinois State Department of Public Health, the tainted milk was the probable cause in two deaths and was implicated in 12 others.[17] This report also indicated that the probable cause of the outbreak was a cross-connection between skim and whole milk that involved a "dead leg" in the sanitary plumbing where the *Salmonella* had most likely thrived for as long as 10 months. However, the details of the study and the probable source of the contamination were never confirmed. This whey powder scare also calls to mind the 2008/2009 outbreak involving peanuts and peanut-containing products from Peanut Corporation of America (PCA) that resulted in more than 700 cases of illness and 9 deaths. Much like whey powder, peanuts and peanut-derived products are used extensively as food ingredients across the entire U.S. food manufacturing industry. This peanut outbreak is likely to have affected food supply chains in nearly every state of the union. In early 2009, CDC and Minnesota public health officials confirmed that peanut butter, also a pasteurized food like whey powder, was the likely source of the outbreak. In that historic outbreak, it was also reported by PCA officials that daily pathogen testing, including tests for *Salmonella*, was consistently negative.[18] This outbreak culminated in congressional hearings where industry executives were called to testify and the eventual closure of PCA's operations in February 2009. The PCA outbreak was a catalyst that would lead to many changes within the food processing industry, and, in particular, how food safety and supply chain protections would be implemented.

Salmonella is a leading cause of reported foodborne illness in the U.S., surpassed only in this distinction by *Campylobacter,* according to a 2017 report from the CDC.[19] The bulk of the morbidity has been attributed to poultry and beef products contaminated with *Salmonella*. It is indeed unusual to encounter *Salmonella* in low-moisture foods, such as crackers and baked goods. While it is widely reported that water activity below 0.93 is growth limiting for *Salmonella*, this does not mean that the organism will perish under such low-moisture conditions.[20] While environmental survival data for *Salmonella* are not definitive, it is generally accepted that these microorganisms are somewhat resistant to harsh environmental conditions. In the Jewel case, for example, it has been speculated by those investigating the outbreak that index organisms had persisted in harborage areas within the manufacturing equipment for as long as 10 months.

The FDA Amendments Act of 2007 (Pub. L. 110-085), Section 1005, directed FDA to establish a Reportable Food Registry (RFR) for industry. The RFR applies to

all FDA-regulated categories of food and feed except dietary supplements and infant formula. Those responsible for registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. under Section 415(a) of the Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

Whey powder is an FDA-regulated food, and, therefore, the company that produced the contaminated product would, in the event of a process deviation or a failure of its Hazard Analysis and Critical Control Points plan involving *Salmonella* (or other pathogens), be obligated to inform the RFR when and if such food was placed into distribution. In this instance, the company reported that in-process test results were all negative for *Salmonella*. Thus, the company was absolved from any reporting requirements. *Salmonella* organisms are heat labile with D_{72} in milk for *Salmonella* Senftenberg reported as 0.09 minutes. By contrast, the D_{72} for *S.* Typhimurium, also in milk, is reported as 0.003 minutes.[21] Thus, normal pasteurization conditions used in whey processing (i.e., temperature in excess of 70 °C for at least 0.25 minutes) would be expected to rid the processed product of *Salmonella*–achieving a 6D reduction (the most heat-resistant strains) at 72 °C would require an exposure time of only 0.54 minutes. For the more heat-labile strains, the same level of inactivation would occur in 0.018 minutes. Therefore, unless there was a gross failure in applying the pasteurization process, it is difficult to conceive a circumstance where properly processed whey would be contaminated with this pathogen. Between pasteurization and packaging, there is an additional heat treatment step involved in the manufacture of whey powder (Figure 1[4]). The fluid whey fraction is typically atomized and spray-dried, whereby droplets within the drying chamber reach a temperature of 50–60 °C, a processing step that represents further lethality for heat-labile microorganisms. Therefore, a more plausible explanation for the *Salmonella* contamination in the whey powder is post-process contamination (i.e., the product was contaminated at some unit operation point downstream of the pasteurizer and spray dryer). Recall that in the Jewel incident, the contamination was attributed to improperly designed milk handling equipment downstream from the point of pasteurization. Post-process contamination is the most plausible failure mode for the recently implicated whey powder. However, this would in fact probably be a contributing cause and probably not the root cause. If we were to use an Ishikawa chart (Figure 2[22]) as an aid in the outbreak investigation, it would become apparent that consideration needs to be focused on the plant's work staff. Recall that *Salmonella*, an enteric pathogen, is most often transmitted via a fecal-oral mechanism. Therefore, one would deduce that a worker with contaminated hands was involved and probably the root cause of the outbreak. Failures in proper hand hygiene are a significant contributor worldwide to foodborne illness outbreaks. Of course, there are other possibilities. A leaking, bird excrement-contaminated roof, for example, was the reported cause of a major outbreak in 2007. Yet again, though, the fecal-oral mechanism is preserved.

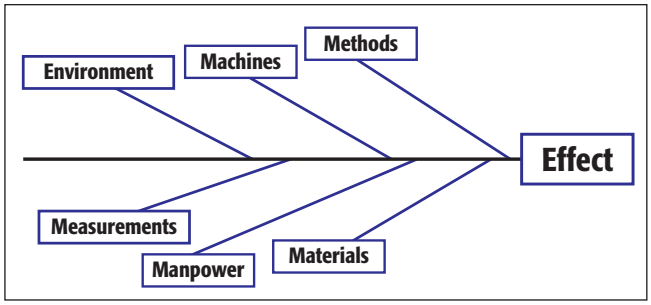

Figure 2. Ishikawa Chart for Failure Mode and Effects Analysis

The concept of food safety can be illusory. There are myriad details and topics that need to be considered in the pursuit of food safety. Achieving food safety demands an exquisite understanding of the food that is being investigated, including its constituent ingredients, methods of manufacture, processing, packaging, storage, and modes of transportation and distribution. Food safety issues most often arise from a failure to properly manage and control the manufacturing processes used in food production. Such failures involve loss of control of process-critical procedures and critical control points during manufacture, and these might include failing to anticipate and plan for post-processing conditions that might place the food or ingredient at risk. Poor equipment design and installation are frequent culprits. For example, transferring a clean, pasteurized food onto or into equipment that has hygienic design flaws is frequently a recipe for disaster.

Food safety cannot be tested for or inspected into a product! Testing and inspecting finished foods seldom add any value in terms of food safety.[23] At that point, the food is either safe or unsafe. In the most recent scare and recall involving whey powder, the manufacturer of the ingredient, according to published reports, analyzed the finished powder and this testing indicated an apparent absence of *Salmonella*. Subsequent analysis of retained samples from the same production lots tested positive for *Salmonella*. Again, the fallacy of sampling and testing for food safety! Rather, validated and verifiable processes would provide information indicating the performance of the entire process and thereby inform the public health status of the product.[24] Validation and verification must extend beyond the pasteurization process (kill step) and include other critical steps in manufacture, including cleaning, sanitation, and hygiene. Key questions might include: Were the manufacturer's cleaning and sanitation procedures validated, and did the sanitation workers verify that the cleaning activities were properly performed and that the results conformed to the established control limits? We currently don't have

detailed answers to these questions, but we do know that the company appeared to erroneously rely on testing of finished product as a confirmation of food safety. As a result of this approach, public health was put at risk, and both the manufacturer of the whey powder and several end-user companies have suffered economic and reputational harm as a result of having to recall their products from the marketplace. ■

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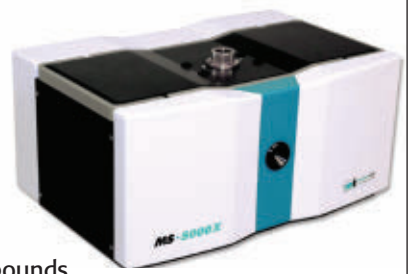

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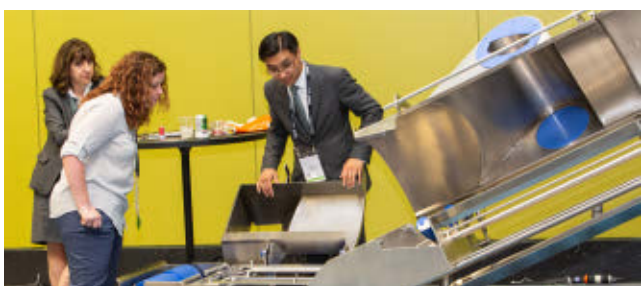

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(continued from page 21)

www.epa.gov/oppad001/list_g_norovirus.pdf.

Cleanup procedures that might result in aerosolization of norovirus (e.g., dry-vacuuming, dry dusting, or buffing) should not be used (Table 2). Cleaning with detergent and hot water, followed by disinfection with sodium hypochlorite or steam cleaning is preferred. Lastly, minimize air currents generated by open windows, fans, or air conditioning because

General Considerations

- At a minimum, wear single-use gloves and a pair of goggles. Additional personal protective equipment includes face mask, single-use gown with sleeves, single-use hair cover, and shoe covers.
- Prepare fresh disinfectant solutions every 24 hours.
- While chemicals are being applied, use appropriate ventilation in areas being disinfected.
- For chemicals, use a pour or pump bottle that does not produce aerosols instead of a spray bottle. This reduces respiratory irritation that can be caused by aerosols.
- Clean and disinfect areas from the lowest incident rate/likelihood of contamination (e.g., tables, countertops, equipment) to the highest (e.g., bathrooms).

Procedural Steps

Hard surfaces

- Clean surfaces with warm water and a detergent to remove soil.
- Rinse surfaces with warm water to remove cleaning products and suspended debris.
- Apply sufficient disinfecting solution to thoroughly cover the entire surface. For example, if cleaning foodservice equipment, be sure to clean legs, sidewalls, and the back of equipment.
- Let the solution stand for the contact time given on the label.
- If the surface being cleaned is classified as a food contact surface, this disinfection procedure should be followed by a clear-water rinse and a final wipe-down with a sanitizing bleach solution (e.g., 200 ppm sodium hypochlorite) or other EPA-approved product.

Soft surfaces that cannot be moved (e.g., carpet, draperies, and upholstered furniture)

- Clean all surfaces with warm water and a detergent.
- Rinse the soapy water from all surfaces.
- Steam-clean the area for 5 minutes at a temperature of 170 °F (76.7 °C). (Not all steam cleaners can reach 170 °F, so check the manufacturing specifications.)
- Soft surfaces can also be disinfected with a bleach solution; however, the bleach will discolor the material.

Linens

- Contaminated linens (e.g., wiping cloths, aprons, tablecloths) should be carefully placed into laundry bags (to prevent generating aerosols) and washed separately in hot water for a complete wash cycle.
- Always wear single-use gloves (and apron or gown) if soiled laundry will touch clothing when handling soiled laundry. Prior to laundering, carefully place all contaminated items that can be washed in a washing machine in a plastic bag, then seal the bag to avoid cross-contamination.
- Machine-wash soiled items in a washing machine using hot water and laundry detergent.
- For loads of all-white items, add 5–25 tablespoons of bleach per gallon of water.
- Dry the just-washed items in a dryer on the high-heat setting.

Table 2: Environmental Disinfection

they may disperse aerosols widely.

As noted above, if contaminated surfaces are not properly cleaned *and* disinfected, they could be a source of norovirus and possibly cause or prolong an outbreak through residual environmental contamination. By following CDC outbreak management and disease prevention guidelines, establishments can significantly enhance their outbreak response, including cleanup of the foodservice environment. ■

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and debris are used. If this is still not effective, then chemicals will need to be applied to the dry cleaning to remove the soils, but water-based cleaning methods should not be introduced.

When challenges arise using just dry cleaning methods and mechanical action, then water may need to be introduced through fully automated circulation cleaning processes. The step change from dry to wet cleaning parameters is best accomplished with the use of CIP. Fully automated cleaning systems work best as they allow control of parameters such as time, temperature, concentration, flow, and mechanical actions along with the repeatability of the cleaning method. Fully automated systems are very well-controlled and take the human element out of the cleaning equation. This works only for pipes, tanks, and similar equipment that is designed as fully CIP.

A controlled wet clean out of place is the next choice of cleaning method to consider. Just like at home, we do not bring in hoses; we set up a controlled wet environment for cleaning. A better scenario than taking items out of place such as utensils, bowls, and small wares to be washed in the sink would be an automated dishwasher. This provides management of the same parameters as discussed with CIP. Lessons from the pharmaceutical industry reveal the importance of controlling water in that reducing the human element in cleaning is important, and automated cleaning provides control of performance and repeatability for cleaning in a food processing environment. Again, eliminating the human process is important. Human elements like experience, and differences in performance and skill sets vary day to day and person to person, creating inconsistency in the cleaning process.

ACS is a manual CIP process without all the bells and whistles of CIP. A process tank may be used to mix the chemistry and then deliver it to the equipment. This method does increase the chance of human error to occur, however.

Controlled wet cleaning in place may need to be used when ACS and CIP cannot be applied. It may not be possible or reasonable to remove all the pieces and parts of the equipment that are in contact with food and need to be cleaned. Just as when wiping off counters at home, areas in the plant that are soiled and need to be cleaned using water should be controlled in isolation to not spread the soil to other pieces of equipment and areas within the plant.

Flood cleaning should be avoided whenever possible. Full flood cleaning spreads the soil, extending the cleaning process beyond the focus areas. This causes the highest risk to equipment, product, and employees through contamination, early failure of equipment, and risk to human safety.

Key Takeaways

Controlling the risks and financial costs of cleaning can be done by developing and implementing the right cleaning methods discussed here. Developing an internal water-control program, like an audit program for glass and brittle plastic, is required to design out that hazard. The goal is to eliminate unnecessary use of water within a production facility. That starts with choosing the right type of equipment.

Training employees about the new WOW program takes time. It is a challenge to change the culture and mindset that a facility needs to be sparkling. There is a difference between the cleaning processes for stuck-on soils of spaghetti served on a plate versus sugar cookies served on a plate. It would be acceptable to brush off the sugar and crumbs on a serving plate and place toast on the same plate rather than giving the plate a full water-and-detergent cleaning. Employees will challenge the thinking of dry cleaning methods. Implementing this new system takes time to change employees' mindset.

It is not uncommon to walk through a facility and see uncontrolled water dripping and pools forming under leaky pipes. The need to train employees not to walk by these uncontrolled-water issues is essential in changing the culture and accepting new cleaning methods. Using the home example again, no one would walk by some plumbing issues like dripping, leaking faucets or pooling water at home. People need to see the water differently at the plant just as they do at home. Employees should be empowered to report the leak, grab a squeegee, and push the water down the drain so the surface can dry. They need to see the controlled-water systems put in place and practiced throughout the facility.

Follow the ranked cleaning-method proposal to minimize the added risk of cleaning. Work collaboratively with sanitation engineers to think about early management. Train engineers so that they are aligned with the different cleaning methods that facilitate dry cleaning, or so they design equipment with parts that are easily removable and can be subjected to an automated cleaning process.

Establish a risk-based framework to ensure that the appropriate cleaning methods and sanitation protocols are applied. Regulators also need to understand how the ranked cleaning methods reduce the risk of microbial contamination. Align the methods with scenarios that reduce the microbial risk profile in the processing facility. Understanding the risks, the right methods, and the right cleaning frequency is essential. What is the proper science behind cleaning? Is it to reduce microbial growth or to reduce pest activity? Science needs to support the step change in pathogen risk reduction as well as significant financial impact to the food and beverage production industry.

Controlling water and treating it like glass is a journey for everyone in the food and beverage industry and a destination that profits everyone, including the consumer. ■

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FOOD SAFETY CULTURE

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Food science, including food safety, needs to be applied together with social and cultural sciences to ensure effective food safety management for consumer and brand protection. A strong food safety culture makes strong business sense and is achieved by properly analyzing business processes and building systems to be proactive and continually evolving rather than reactive and static. This includes utilizing the social science toolbox to engage the workforce using transparent and effective communication to share and establish company values and personal commitments. In this way, it is possible to drive food safety forward and continually improve standards, making food safety a habit for every employee every day. ■

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SPOTLIGHT

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STEC causing foodborne illness included within courses in food science and human nutrition. Additional workshops at the Souderton Area School District (SASD) resulted in initial steps in implementation there. To build the pipeline of future professionals, the project further partnered with SASD to promote and expand their Pathway 360° Program, which engages students from 8th to 12th grades and includes career exploration courses, job shadowing, mentorship, and presentations. A series of three graphic novels as an innovative educational method to introduce food safety education into the curricula of middle school students was developed and published.[6]

The Office of Educational Innovation and Evaluation at KSU has provided assessment and evaluation. They monitored outputs using a number of parameters and conducted surveys of students, collaborators, and members of the STEC CAP Stakeholder Advisory Board (SAB) to assess accomplishments, strengths, weaknesses, and impacts of the project, in addition to interactions among STEC CAP participants and the SAB.

Conclusions

The STEC CAP has had major, cross-functional impacts on beef safety research and education, with positive public health implications continuing for years to come. With targeted research, outreach, and communication goals and mechanisms, the evidence-based work of NIFA and STEC CAP has extended into multiple communities across several states and universities through this strategic partnership.

The STEC-CAP is led by an executive management team that includes me; Randall Phebus, KSU; John Luchansky, USDA ARS, Eastern Regional Research Center; Daniel Gallagher, Virginia Tech University; and Harshavardhan Thippareddi, University of Georgia. Jill Hochstein, UNL, is the project manager. Drs. Jeanette Thurston and Isabel Walls at the USDA-NIFA have served as National Program Leaders in support of the STEC CAP. ■

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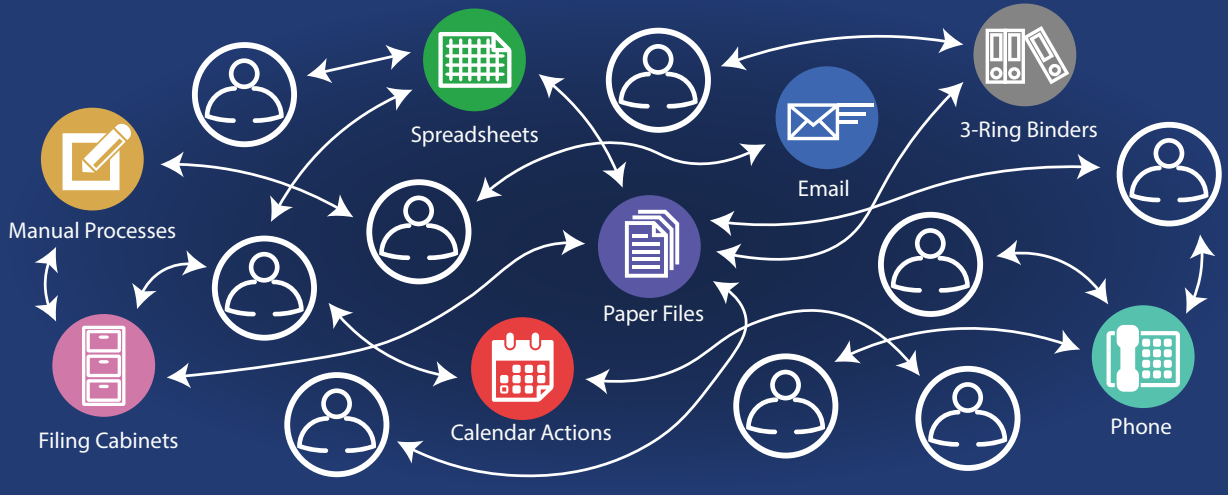

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