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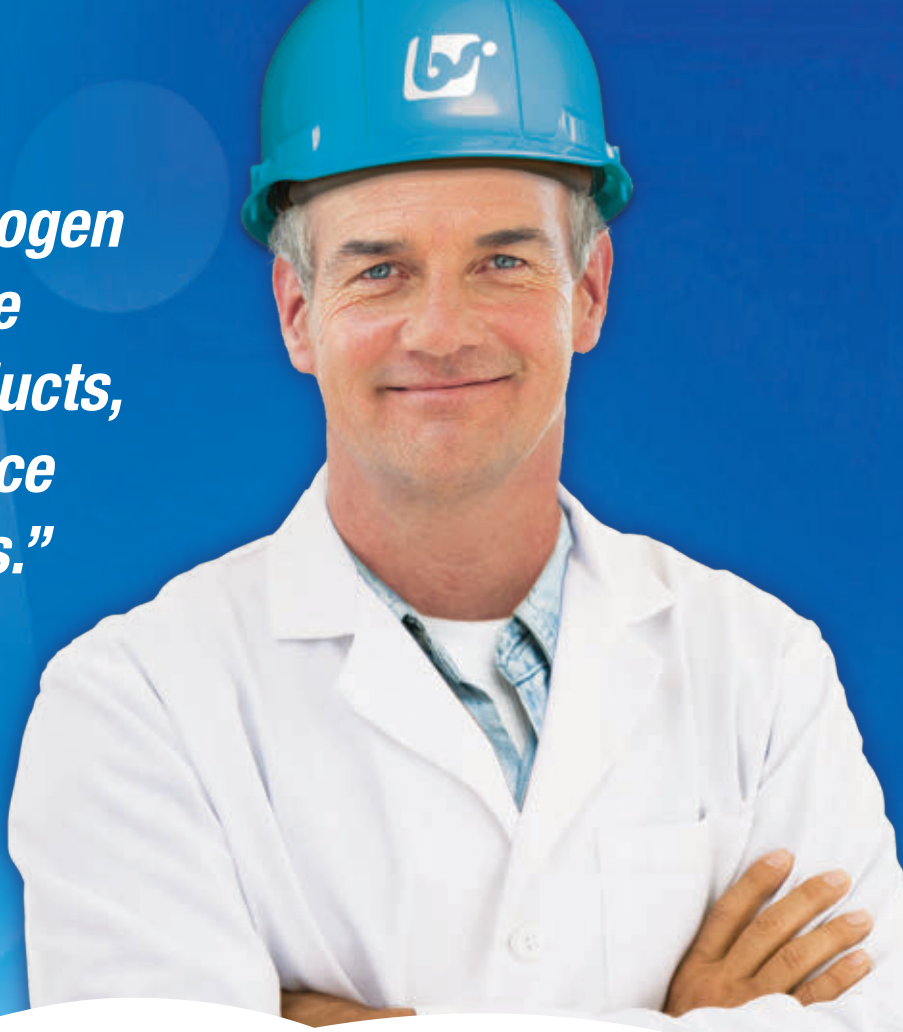

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Editor's Letter

Shakespeare Denied

"Not that I loved Caesar [salad] less, but that I loved [spinach] more."

As I write this, the U.S. (and our neighbors in Canada) is in the midst of a widespread outbreak of *Escherichia coli* O157:H7 infections most likely linked to romaine lettuce. This news broke widely in the mass media over the Thanksgiving holiday, when most people were thinking instead of turkey and pumpkin pie rather than salad.

But long after the leftovers were gone (thanks to my ravenous home-from-college offspring), I had a hankering for a big spinach salad…so off to the grocery store I went.

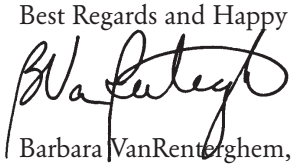
Imagine my surprise when I found ABSOLUTELY NO LEAFY GREENS OF ANY SORT in the produce section. No containers of spinach, no heads of iceberg lettuce, no bagged products except coleslaw, no red or green leaf lettuce or arugula…NOTHING.

What was I missing? Once back home, I quickly scoured pages on the U.S. Food and Drug Administration (FDA)'s website, thinking that I had missed a more sweeping announcement of the recalled products. But all I could find was the recall of romaine lettuce and bagged salad products containing romaine. Why then did my store strip all leafy greens from the shelves? Was it a preponderance of caution? Miscommunication? Is it because this outbreak is closely related genetically to the *E. coli* strain isolated from ill people in a 2017 outbreak linked to leafy greens in the U.S.? I'm still not sure.

It's been 6 days since the initial announcement of this recall. The consumer advisory not to eat romaine lettuce has just been lifted, based on a new voluntary labeling agreement reached with industry. FDA's objective with this labeling agreement is to provide consumers with clear information as to where their romaine was grown and when it was harvested. While no source has yet been identified and the outbreak has not been declared over, perhaps unaffected products will be returned to their rightful places on retailers' shelves in the near future.

In the meantime, Brussels sprouts, anyone?

Best Regards and Happy Holidays,



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Larry Keener Earns IUFoST Lifetime Achievement Award

Larry Keener, a member of *Food Safety Magazine*'s Editorial Advisory Board, was surprised with a Lifetime Achievement Award from the International Union of Food Science and Technology (IUFoST). His work in food science, technology, and food safety was honored at IUFoST's 19th Annual World Congress of Food Science and Technology in Mumbai, India, in October 2018. The award was given to Larry by India's Honorable Minister of Food and Food Processing Harsimrat Kaur Badal. In addition to accepting this award, Larry participated at IUFoST by presenting a plenary session talk on technology and poverty reduction. He also convened a workshop on validation and food safety.

BizTracks

Bio-Rad Wins USDA Contract for Pathogen Detection Products

Bio-Rad Laboratories Inc. has announced that the company has been awarded a contract for its iQ-Check real-time PCR pathogen detection test kits and the iQ-Check Prep Automation System from the U.S. Department of Agriculture Food Safety and Inspection Service.

Mandernach Joins *FSM* Board

Steven Mandernach has joined the Editorial Advisory Board of *Food Safety Magazine*. Mandernach is the executive director of the Association of Food and Drug Officials (AFDO). Prior to becoming executive director in 2018, he was the bureau chief for Food and Consumer Safety at the Iowa Department of Inspections and Appeals. Mandernach is a past president of AFDO and currently cochair of AFDO's Laws and Regulations and Administration Committees. He also serves on the advisory board for George Washington University School of Medicine and Health Sciences' Regulatory Affairs Program. Additonally, he was appointed 2017–18 ambassador to public health for the State Hygienic Laboratory at the University of Iowa.

Mandernach graduated with a J.D. from Drake University Law School and a B.A. from Buena Vista University. He has completed graduate work in food safety at Michigan State University. Mandernach served for 10 years as adjunct instructor of business law and political science at Des Moines Area Community College.

IFSAC Releases New Report on Sources of Foodborne Illness

The Interagency Food Safety Analytics Collaboration (IFSAC) recently released a report entitled *Foodborne Illness Source Attribution Estimates for 2016 for* Salmonella, Escherichia coli *O157*, Listeria monocytogenes, *and* Campylobacter *Using Multi-Year Outbreak Surveillance Data, United States*. The authors used outbreak data to produce new estimates for foods responsible for foodborne illnesses caused by four pathogens in 2016. The U.S. Centers for Disease Control and Prevention estimates that, together, these four pathogens cause 1.9 million foodborne illnesses in the United States each year.

The analysis uses a method developed by IFSAC to estimate foodborne illness source attribution, which is the process of estimating the degree to which specific foods and food categories are responsible for foodborne illnesses. In addition to the 2016 estimates, IFSAC posted estimates for 2014 and 2015 on its website, reflecting IFSAC's goal to provide annual updates of these estimates using data from the most recently available outbreak data.

For the 2016 report, available at www.foodsafetymagazine.com/news/ifsac-releases-new-data-on-sources-of-foodborne-illness/, IFSAC analyzed data from just over 1,000 foodborne disease outbreaks that occurred from 1998 through 2016 to assess which categories of foods were most responsible for *Salmonella*, *E. coli* O157, *L. monocytogenes*, and *Campylobacter* infections. These pathogens were chosen because of the frequency or severity of the illnesses they cause, and because targeted interventions can have a major impact in reducing them. The implicated foods were divided into 17 categories for the analysis, and the method gives the greatest weight to the most recent 5 years of outbreak data (2012–2016).

The updated estimates combined with other data might help shape agency priorities and support the development of regulations and performance standards and measures, among other activities. As more data become available and methods evolve, attribution estimates may improve. Updates to these estimates will enhance IFSAC's efforts to inform and engage stakeholders, and further their ability to assess whether prevention measures are working.

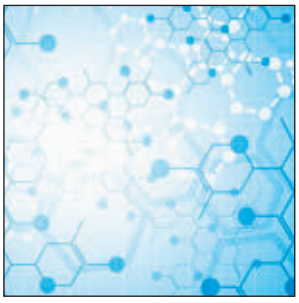
ONLINE & OF NOTE

www.mpi.govt.nz/food-safety/

New Zealand's Ministry for Primary Industries (MPI) leads the country's food safety system, protecting the health and well-being of consumers globally. MPI helps guard the international reputation of New Zealand food products by setting and monitoring food standards.

By Tania Portolés, Ph.D.

Using APGC to Improve Food Contaminant Monitoring



Analysis of contaminants in the food supply requires advanced technology

Chemical contaminants may occur in our food from various sources. This is a result of various stages of production, processing, transport, or the environment. As these chemicals can be harmful to human health at higher concentrations, the use of many contaminants is limited by the European Union. Therefore, analyses of these contaminants in food samples are essential to ensure consumer safety and compliance with regulatory limits.

Environmental Contaminants

Contaminants are either man-made or naturally occurring substances that are present in the environment and bioaccumulate in the food chain. Examples of contaminants that enter the food chain include brominated flame retardants (BFRs), polychlorinated biphenyls (PCBs), and polycyclic aromatic hydrocarbons (PAHs) (see "A Closer Look at Food Contaminants," p. 10).

BFRs are man-made chemicals that are added to a wide variety of products, including for industrial use, to make them less flammable. These harmful compounds leach into the environment and pollute the air, soil, and water through waste residues or discharge from the factories that produce them.[1] As a result, the use of certain BFRs is banned or restricted in many countries.

BFRs enter the food chain when they reach the marine environment, as they are consumed by fish and shellfish, and cannot be excreted because they are lipophilic. This means that high levels can be present in seafood destined for human consumption.

PCBs also had widespread use in a range of industrial applications until they were banned in most countries in the 1980s, but they remain in the environment today as a result of their high stability. At high levels, they have been shown to cause health problems including carcinogenesis, endocrine disruption, and neurological problems.[2]

PAHs are generated mainly as a result of pyrolytic processes, especially the incomplete combustion of organic materials such as coal, oil, petroleum, and wood.[3] PAH exposure and its effects on human health have also been the focus of many studies, and some PAHs have been shown to be carcinogenic and mutagenic. The monitoring and regulation of PAHs are under constant change by advisory bodies such as the U.S. Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health that stipulate exposure limits for PAH content.

As a result of the changing regulatory landscape, there is need for more accurate identification and quantification of contaminants in environmental and food-related samples. Modern analytical techniques provide scope to remove contaminants from the food chain by obtaining unambiguous and highly accurate quantification of contaminants in complex food matrices at low concentrations. They can also be used to identify new or unexpected contaminants.

A technique for detection and quantification of contaminants in food samples of marine origin has been developed by researchers at the Research Institute for Pesticides and Water (IUPA), University Jaume I, in Spain. The aim was to develop advanced analytical methodology to improve the monitoring of compounds in food samples. Using atmospheric pressure gas chromatography (APGC), an innovative method was developed that is very ef-

fective for identifying and quantifying contaminants.

Soft Ionization

Electron ionization (EI) has traditionally been used as an ionization technique to identify BFRs and other persistent organic pollutants. However, the technique's limitations include extensive fragmentation and the absence or low intensity of the specific molecular ion. This lack of specificity makes the identification of these compounds difficult and can also reduce the technique's sensitivity.

IUPA is utilizing a new chemical ionization source, APGC, that results in a "soft" ionization process to resolve the drawbacks of EI. The increased sensitivity enables quantification and confirmation of trace components at lower levels in the most complex samples.

The analysis of food samples by APGC enables improved selectivity when generating multiple reaction monitoring (MRM) transitions in comparison with the significant fragmentation experienced with an EI source. Operating the gas chromatography system at atmospheric pressure provides increased scope for ionization modes–namely charge and proton transfer.

Method Development and Validation

Using the APGC technique, IUPA collaborated with the Institute of Aquaculture Torre la Sal in Spain and the National Institute of Nutrition and Seafood Research in Norway to develop and test a method that would increase the number of contaminants detected, at much lower concentrations than previous methods reported, in a variety of food samples.

The method uses gas chromatography coupled to a tandem quadrupole tandem mass spectrometer with an atmospheric pressure chemical ionization source. The method is based on a modification of the unbuffered QuEChERS method (quick, easy, cheap, effective, rugged, and safe).

IUPA used APGC for GC-tandem mass spectrometry (GC-APGC-MS/MS) analysis of PAHs, PCBs, and pesticides in 19 different matrices–including fish tissues, feeds, and feed ingredients.[4]

Sustainable plant-based feeds developed for marine fish farming have presented new challenges concerning contaminants. Unrefined plant oils obtained from oilseeds such as soybeans, rapeseeds, olive seeds, and sunflower seeds are known to contain elevated levels of PAHs.

The carcinogenic "heavy" PAHs (> 4–6 rings) have attracted extensive interest with regards to food safety. Studies related to plant oil PAH contamination, however, mainly focus on light (2–4 rings) PAHs, such as fluoranthene,

naphthalene, anthracene, and phenanthrene, as they are most dominantly present in unrefined plant oils. These light PAHs are also on the U.S. Environmental Protection Agency list for environmentally relevant PAHs but are mostly neither carcinogenic nor genotoxic.

In addition to the 24 PAHs, researchers tested for 15 pesticides and seven PCB congeners to widen the scope of the method. The study was to determine trace levels (as low as 0.1 ng/L) of PAHs, PCBs, polybrominated diphenyl ethers, and some emerging flame retardants.

The team used a total of 76 samples from 19 different matrices. The list contains ingredients from different origins (plant, terrestrial animals, and marine) and feeds based on these ingredients, as well as fillets of Atlantic salmon and gilthead sea bream reared on these feeds.

The high sensitivity of this technique allowed the simultaneous quantification of 19 different complex matrices from aquaculture using solvent calibration. The excellent sensitivity and selectivity provided by GC-APGC-MS/MS allowed the dilution of the sample extracts and quantification using calibration with standards in solvent for all 19 matrices tested.

Analysis of real-world samples revealed the presence of naphthalene, fluorene, phenanthrene, fluoranthene, and pyrene at concentration levels ranging from 4.8 to 187 ng/g. Studied PCBs, dichlorodiphenyltrichloroethane, and pesticides were not found in fillets from salmon and sea bream. The aim of this work was the elimination of matrix effects. Even so, limits of quantification of the developed method were 2 ng/g for most analytes in the same order, or better than those reported in previously published methods for similar matrices showing higher efficiency.

Increased Sensitivity and Selectivity

The research determined that APGC is a robust and sensitive technique to analyze a broad range of contaminants in several marine-based matrices.[5] The possibility of selecting the molecular ion or the protonated molecule as a precursor ion for MRM experiments provides greater sensitivity and selectivity. This allows for the dilution of the sample extracts and quantification using calibration with standards in solvent, so matrix-matched calibrations can be avoided in some cases.

Increased sensitivity enables quantification and confirmation of trace components at even lower levels in the most complex samples. The ability to eliminate the matrix effect thereby eliminates the need for time-consuming purification steps. The sensitivity and selectivity also reduce the cost of tests for contaminants.

The technique uses fewer solvents and materials in comparison with previous techniques. The ability to determine compounds at a lower concentration allows compliance with regulatory limits and the ability to inject less sample matrix, reducing effects of contamination on the GC-MS system and therefore increasing uptime.

Soft ionization is a key benefit because of the reduced fragmentation for many compounds when compared with techniques such as EI. Reduced fragmentation can give higher sensitivity and specificity, therefore simplifying precursor ion selection in MS/MS analyses.

The soft ionization that occurs in the APGC source generates spectral data typically rich in molecular or protonated molecule ion information. This notably facilitated the application of MS/MS methods and also the screening of contaminants with GC-MS, focusing the search to the highly diagnostic molecular ion.

The versatility of the technique is high because it is possible to have both GC and liquid chromatography (LC) coupled to the same mass spectrometer, and it is relatively quick and easy to change from LC to GC and vice versa.

Researchers are keen to understand more about the capabilities that APGC can provide. In particular, low-level detection is fundamental as researchers are often searching for the unknown in complex and challenging samples.

The research undertaken using the innovative APGC technique provides great opportunities for food security in terms of improving monitoring pollutants and meeting stringent safety standards. ■

***Tania Portolés, Ph.D.**, is a researcher at the IUPA, University Jaume I, Spain.*

A Closer Look at Food Contaminants

Food contaminants are chemical substances that have been unintentionally added to food or feed, and can accumulate in the food chain. The major classes of contaminants include mycotoxins, heavy metals, dioxins and polychlorinated biphenyls, polycyclic aromatic hydrocarbons, 3-monochloropropanediol, melamine, erucic acid, and nitrates.

A number of analytical techniques are used in food safety testing. These include advanced instrumental techniques such as infrared spectroscopy, nuclear magnetic resonance, and mass spectrometry. Mass spectrometry is a versatile detection approach and is one of the most commonly employed tools for food safety testing, as it produces both qualitative and quantitative data, and allows detection of low concentrations of analytes in complex matrices.

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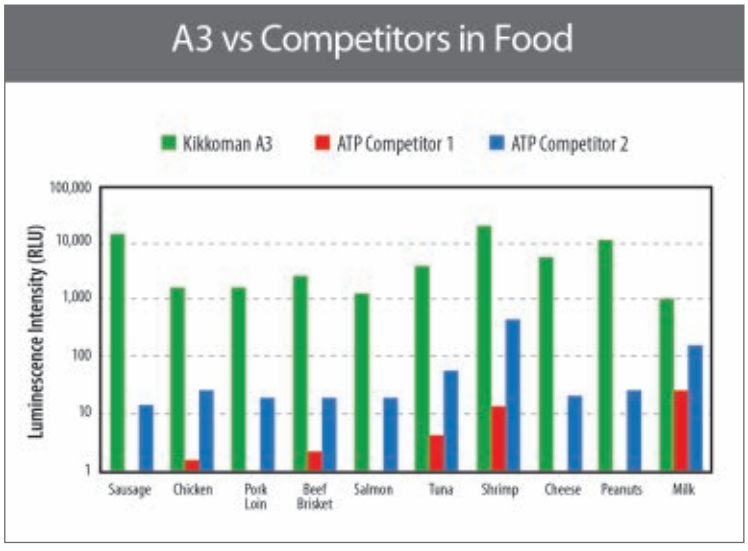

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By Dr. Ramakrishnan Nara

Microplastic Contamination of the Food Supply Chain

Data indicate rising consumption levels worldwide –and a need for action

According to the U.S. National Oceanic and Atmospheric Administration (NOAA), microplastics are small plastic pieces less than 5 mm long that can be harmful to marine and freshwater organisms. A variety of sources have been cited for microplastic pollution, such as dumping of plastic waste into the oceans that degrades slowly and the use of microbeads as exfoliants in beauty products. Because of their tiny size, these pollutants escape water filtration systems and end up either in the oceans or in other water bodies, and cause serious environmental and food safety concerns. Extensive and indiscriminate use of food packages and drink bottles, synthetic textiles, car tires, paints, personal care products (e.g., facial cleaners, toothpaste), and electronic equipment is also one of the main contributors to microplastic contamination of the environment and food chain.

According to Worldwatch,[1] the consumption of plastics worldwide has been increasing at an alarming rate. North America consumes approximately 100 kg/person of plastic each year, mostly in the form of packaging, as opposed to 20 kg/person in Asia. The global production of plastics was 335 million metric tons in 2016. According to the United Nations Environmental Program (UNEP),[2] more than 8 million tons of plastic leak into the ocean each year–equal to dumping a garbage truckload of plastic every minute. Also, plastics for recycling are shipped to less-developed countries for reprocessing; they become an important source of air and water pollution. UNEP recently launched a global campaign to eliminate major sources of marine litter by 2022: microplastics in cosmetics and single-use plastic. Launched in 2017 at *The Economist* World Ocean Summit in Bali, the "CleanSeas" campaign is urging governments to pass plastic reduction policies, targeting industry to minimize plastic packaging and redesign products, and calling on consumers to change their throwaway habits–before irreversible damage is done to our seas.

What Makes Plastics Problematic?

Chemically, plastic is a polymer, a molecule that consists of repeating identical units (homopolymer) or different subunits in various possible sequences (copolymer). Plastics are categorized as thermoplastics (plastics that soften on heating and therefore can be molded into different shapes) and thermosets (plastics that cannot be molded on heating). Both types of plastics are relevant for causing pollution of marine and freshwater organisms. Further, to improve the properties of plastic materials, numerous chemicals, such as fillers, plasticizers, colorants, stabilizers, and processing aids, are used. These chemicals are also relevant for polluting the food supply chain.

Microplastics include particles of varying size, shape, and chemical composition. The working group on the occurrence, effects, and fate of microplastic marine debris, hosted by NOAA in 2008,[3] suggested an upper size limit of 5 mm for microplastics, based on the available scientific evidence that it would include a wide range of small particles that could readily be ingested by marine organisms, and such particles that might be expected to present different kinds of threats.

Sources of Microplastic Contamination of the Food Supply Chain

Although hundreds of thousands of plastic materials are in use globally, only

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six are extensively used–polyethylene (PE, high and low density), polypropylene (PP), polyvinyl chloride (PVC), polystyrene (PS, including expanded PS or EPS), polyurethane (PUR), and polyethylene terephthalate (PET).

The production chain for the most common artificial and natural polymers is illustrated in Figure 1[4].

When we assess the impact of microplastics on the food supply, we must make a distinction between primary and secondary microplastics. Primary microplastics are those materials that were originally manufactured to be that size. On the other hand, secondary microplastics are degradation products of plastic materials from larger items. This distinction will help us evaluate the sources of contamination, work out mitigation strategies, and reduce their input into the food supply chain. Primary sources include plastic powders in molding, microbeads in cosmetic formulations, and plastic nanoparticles in a variety of industrial processes. In addition, virgin resin pellets are widely used during plastics manufacture. Secondary microplastics originate from the fragmentation and weathering of larger plastic items. This can happen during the life cycle of plastic products such as textiles, tires, etc.

This article is not concerned with naturally occurring biopolymers because they are biodegradable and therefore do not pose any threat to marine organisms and the food supply chain. Natural polymers are readily biodegraded into CO_2 and H_2O in the oceans.

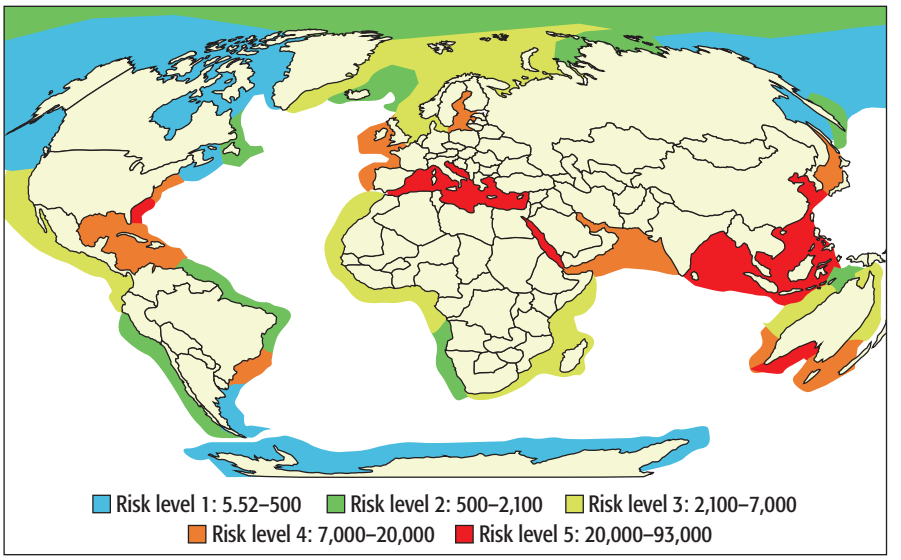

Figure 2. Extent of Microplastic Contamination of the Oceans (Number of Pieces per km²)[5]

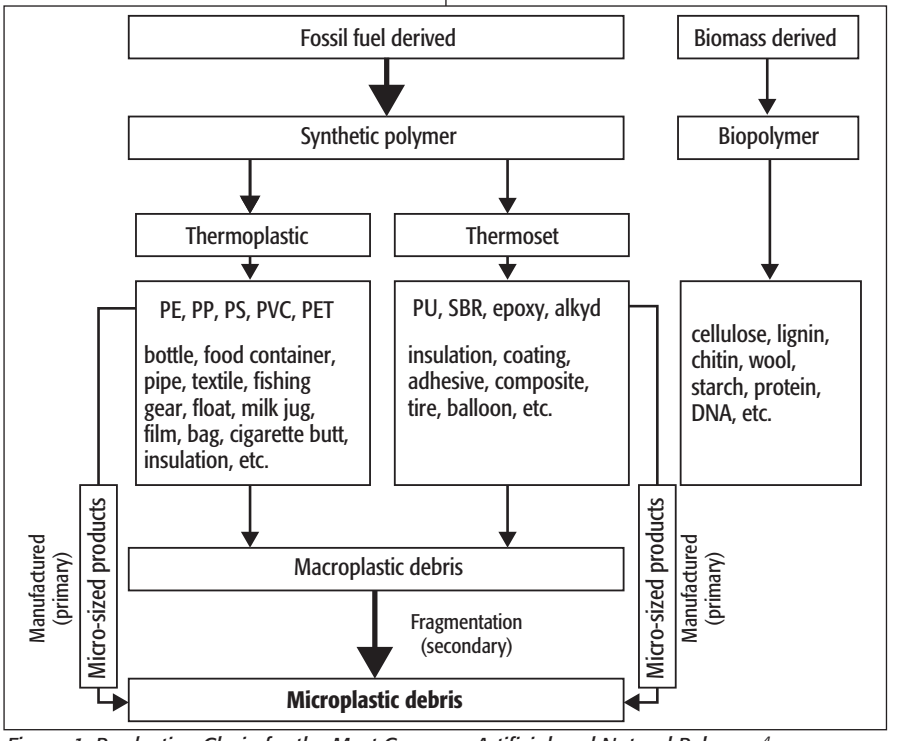

Figure 1. Production Chain for the Most Common Artificial and Natural Polymers[4]

Mapping of Microplastic Contamination

Scientists have used theoretical and numerical modeling to map the extent of microplastic contamination of the oceans. These approaches involve deriving an estimate based on known factors such as sources, transport by ocean currents, sinkability, etc. Figure 2[5] provides an idea of the extent of ocean contamination by microplastics.

Mode of Accumulation of Microplastics in Marine and Freshwater Organisms

Microplastic contamination of marine and freshwater organisms occurs worldwide. Microplastics are highly persistent in the environment and may pose a serious threat to marine and freshwater organisms, as well as to humans because humans are at the end of the food chain. Ingestion of water contaminated with microplastics is the main exposure route for several marine and freshwater species. Recent research has concluded that microplastic ingestion has been observed in fishes, bivalves, and crustaceans. In addition to contaminated water, aquaculture systems where fish or other farmed species are fed with feeding materials produced from fish and other animals (e.g., fish meal) may also be contaminated with microplastics present in these products.[4]

Another route of accumulation of microplastics is external exposure when microplastics contact the outer surfaces of the organism and are translocated from the outside into the organism. The extent of external exposure depends on the concentration and size distribution of the microplastic particles and upon the specific nature of the organism.

Microplastic Contamination of Food Products

Recent studies on microplastics in seafood have confirmed that commercially important fish species such as Atlantic cod and Atlantic horse mackerel are often contaminated with microplastics.[6] According to the Food and Agriculture Organization of the United Nations,[7] of the 25 fish species of commercial significance, 11 were found to contain microplastics.

Several researchers have conducted extensive surveys on the extent of contamination of marine and freshwater species with microplastics. Foremost among them was the study conducted by van Cauwenberghe and Janssen,[8] who calculated that in European countries with high shellfish consumption, consumers ingest up to 11,000 microplastic particles per year, whereas in countries with low shellfish consumption, consumers ingest an average of 1,800 microplastic particles per year. The European Commission's Rapid Alert System for Food and Feed's portal and the European Food Safety Authority's website report the presence of these contaminants in a wide variety of human food items.[9,10]

Studies have also been conducted on the concentration of microplastics in other food products, such as beer, honey, salt, drinking water, and mineral water.[6]

Microplastics and Food Safety

The study of microplastic contamination of food products and its impact on human food safety is an emerging field, and there are many gray areas. Risk associated with ingestion of microplastics into the human body is a function of hazard and exposure. Evaluating the risks from microplastics requires knowledge of the hazard (the potential to cause adverse effects), exposure levels (the quantities detected in human food), and their effects (the identification of dose-response relationships and threshold levels).

Microplastics may act as vehicles or carriers for environmental contaminants and other chemicals that are added during their manufacturing process. Chemicals such as styrene, toxic metals, phthalates, bisphenol A, polychlorinated biphenyls, and polycyclic aromatic hydrocarbons may be absorbed on the

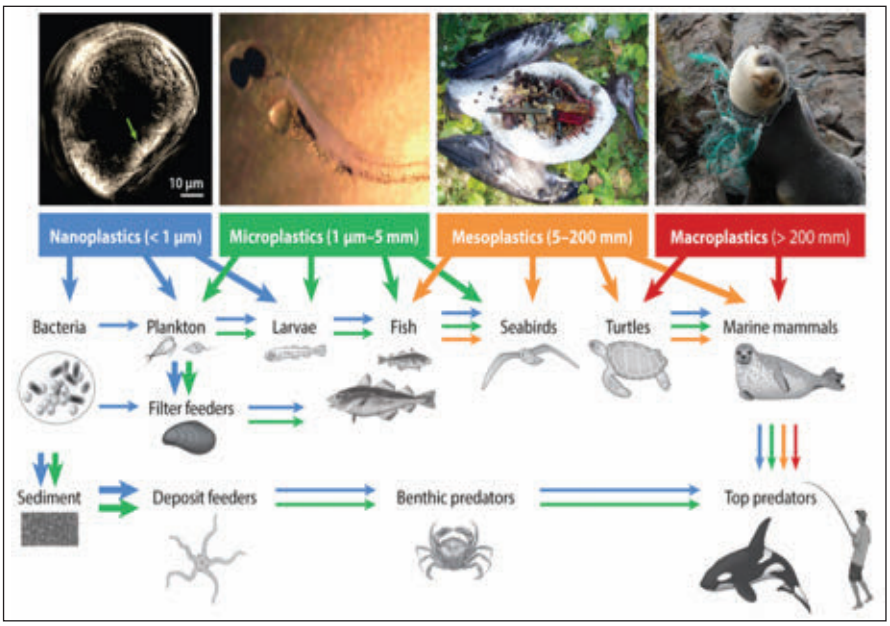

Figure 3. Microplastics in the Food Chain[11]

surface of microplastics and may act as "substrates." These pollutants and additives can be transferred from ingested microplastics to animal tissues and cause impairment of key body functions.

Dumping of plastic waste in the ocean is a global practice. Monitoring studies have established the presence of pathogenic bacteria such as *Vibrio* spp., *Escherichia coli*, and *Bacillus cereus* on plastic debris. The scientific community has expressed concerns about new contamination routes for the introduction of pathogens into the food supply via microplastics. It is still unknown whether pathogenic organisms on plastic debris survive until the end of the food chain.

The risk assessment of microplastics in food safety is still in its infancy, and additional information regarding their occurrence, risk assessment, and mode of action is needed to include them as potential hazards in a food safety plan.

How Do Microplastics Get into Food Systems?

Plastic debris, whether on land or in the sea, has an adverse impact on all forms of life. Plastics enter the food chain when they degrade, and the rate of degradation depends on a variety of factors, such as the chemicals added during the manufacturing of plastic and the physical environment that surrounds them (presence of salt, water temperature, light intensity, etc.). Information about how various types of plastics break down into microplastics in the environment and get into the food chain is scanty. However, it has been established that microplastics enter the food chain when animals eat or ingest contaminated food materials. The food web is extremely complex. Zooplankton, the microscopic sea organisms at the bottom of the food chain, is eaten by all kinds of fish. Fish ingest small pieces of plastic due to their continuous uptake of water. Microplastics get into the next level of the food chain when other animals eat fish contaminated with microplastics. Eventually, microplastics move all the way up to the top of the food chain. This has been well documented (Figure 3[11]).

Effect of Microplastics on Human Health

It is evident that the potential accumulation of microplastics in the food

chain could have adverse effects on human health like other chemical contaminants relevant to food safety. Studies have confirmed unusually high levels of microplastics in seafood. Therefore, there is no doubt human beings are exposed to higher levels of microplastics. Several studies have confirmed adverse effects on animals as follows:

- Reproduction in marine animals is affected by exposure to polystyrene microplastics[12]
- Endocrine disruption in adult freshwater fish from ingestion of PE[13]
- Altered gene expression was observed in male fish exposed to plastic

However, there is still a knowledge gap regarding the specific threats, toxicities, and adverse health effects in humans posed by the ingestion of microplastic-contaminated food.

Conclusion

Microplastic contamination in the food chain has kindled a lot of interest recently among consumers and the scientific community alike. The information available currently on the potential adverse effects of microplastics on human health is scanty and sporadic. Additional research is needed to evaluate the extent of microplastics in the food chain. The scientific community should come up with qualitative and quantitative data including the type, size, and components of microplastics in the food chain.

Currently, there is no regulatory requirement globally to increase human food safety against plastic contamination, due to a lack of qualitative and quantitative information on the levels of microplastics in various foods, their adverse effects on human health, and a lack of effective and comprehensive mitigation strategies to control microplastic contamination. Baby steps are being taken to mitigate the microplastic contamination of the ecosystem. President Barack Obama signed the Microbeads-Free Waters Act in 2015 that banned microbeads from rinse-off cosmetics. In order to reduce microplastic contamination of the ecosystem, global companies such as Johnson & Johnson and Unilever made a commitment that their products would be plastic-free within the next few years and that they would use natural substitutes instead. Other cosmetic companies have come forward to phase out microplastics too.

The most prudent approach is to reduce the problem at its source, namely, reduce the use of plastics in our daily life. This will collectively need the involvement of the society we live in, companies that produce plastics, and regulatory bodies. We should act without further delay to protect our food chain. ■

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By Richard Brouillette and Thomas Haley

The Evolution of Sanitation and Hygienic Design in Bakeries

How to mitigate food safety risks to bakery products

As mentioned in a previous article, the term "bakery" is loosely used to identify a facility that produces a range of products like sliced breads, croissants, filled doughnuts, pies, cookies, decorated cakes, etc. Many of them will have a different microbial risk profile, different allergen profiles, and different types of equipment and infrastructures. All these differences lead to the need for different equipment design and cleaning methods. In this article, we will discuss progress made in design and cleaning methods in recent years.

If we begin with a product risk profile, facilities that did not already have Hazard Analysis and Critical Control Points plan in place needed to gain a better understanding of the different hazards (biological, chemical, and physical) and the risk profiles of their ingredients, processes, and finished products under the Food Safety Modernization Act. In most cases, this is forcing the industry to take a second look at their practices for all aspects of their supply chain, including their own manufacturing locations. For this article, we will focus on the sanitation and hygienic design of bakeries.

What Are the Risks?

The bakery industry is gaining a better understanding that there are hazards associated with its products and that the oven, always considered the "great equalizer," is effective only for some microbial hazards introduced before the oven. There is a greater awareness that under certain conditions, toxins may be produced by organisms such as *Staphylococcus aureus* or *Bacillus cereus*, and that these toxins will survive the oven and may make consumers sick. For processors of products in which these organisms can flourish, hygienic design and cleaning and sanitizing procedures for their equipment before the oven are as critical as the ones for the equipment after the oven.

While allergens are still the number one reason for recalls affecting bakeries, and although equipment cleaning is not often the root cause, there is growing awareness that poor cleaning practices should not become a contributing factor in allergen recalls. Aiding in the validation of the effectiveness of a facility's cleaning methods, there has been a greater use of allergen test kits to test food contact surfaces rather than to rely only on the testing of finished products to validate allergen changeovers.

Finally, physical hazards such as extraneous material can be introduced by equipment located before and after the oven, so selecting and reviewing equipment for hygienic design can be critical. However, there are more reasons to procure more hygienically designed equipment.

Consumers do not always follow the cooking instructions on the food package and may consume products that should be baked without doing so, such as cookie dough. With the increased use of social media in our society, consumers can reach a broader audience when they believe that a food has harmed them or made them sick. Therefore, it is important for processors to continuously improve the quality of their products.

Advances in whole-genome sequencing are helping the regulatory agencies

of many countries identify potential sources of microbial contamination much more rapidly than in the past. You obviously do not want your facility to be identified as a source of a foodborne illness outbreak.

With a low unemployment rate, it has become increasingly difficult to develop and retain a trained workforce to perform sanitation tasks. Also, sanitation is often done overnight or on weekends and holidays, so it is not an attractive vocation for all individuals. Not having people who are accustomed to cleaning the same equipment week after week and who know those difficult-to-clean parts and areas may lead to issues. These challenges are somewhat compounded by the fact that many experienced sanitors are now entering retirement age, creating a gap in knowledge, especially if the equipment is not easy to clean and the cleaning procedures (Sanitation Standard Operating Procedures, SSOPs) are not well written. We see younger employees with different skills joining the workforce.

Most companies are also always looking for ways to improve their productivity or are asked by their customers to do so. Equipment that is less complicated to take apart and has fewer parts is usually easier to clean and allows for faster changeovers. If faster changeovers can be converted into making more products, then the line becomes more profitable.

Mitigating Those Risks

Equipment Design

So, let's begin with equipment design. There is an increasing level of awareness about hygienic equipment design that seems to be driven in part by regulatory expectations and also by a sharing of information between different industries. Some bakery original equipment manufacturers (OEMs) are becoming more dedicated to increasing the hygienic design aspect of their equipment. While there are checklists such as the Grocery Manufacturers Association (GMA)'s equipment design checklist for low-moisture foods that can assist with evaluating the design of existing and new equipment, we should not forget some simple concepts.

The first concept to consider when evaluating a piece of equipment for cleanability is "*If you can't see it, you can't clean it or inspect it!*" Put yourself in the shoes of the sanitor who has to clean it and try to determine how you would do it yourself:

- Could you access all parts of the equipment to scrub them?
- If tools are needed to remove a part, do you need one tool or several?
- How difficult would the equipment be to reassemble?

These may look like simple questions, but if you were the sanitor who

tries to accomplish their tasks in the time given to them, would you be able to execute them? One solution is to take complex pieces of equipment and reengineer them to simplify them.

For new equipment, this would require the OEM to revisit the drawings to identify parts that may not be needed, from simple things such as the number of bolts needed to hold a safety guard in place (if you are wondering, the general answer is one) to the type of side guard needed to prevent product from falling off the conveyor belt (can the product be conveyed in a trough conveyor?) to the number of rollers needed on a conveyor to the number of scrapers needed, etc.

For existing equipment, it is as much making sure the equipment is not modified to be more difficult to clean or less hygienic (e.g., drilling holes in a tubular frame) as it is to think about replacing worn parts with a different model that is more hygienic (e.g., replacing a bearing with maintenance-free, wash-down bearings).

If tools are needed to disassemble a part for cleaning, can one tool serve for all the different parts? This is especially important to consider on legacy equipment that may have gone through different repairs and modifications over the years (Figure 1). It is not unusual to see equipment requiring an entire toolbox to disassemble. There could be efficiency gains realized by making attachments more uniform, for sanitation and for maintenance, production, etc.

Finally, some parts can be very similar, yet they may attach to different places on the equipment. Having some identification system to differentiate the locations would help the sanitor and maintenance when the time comes to reassemble all the parts.

Figure 1. Example of modifications leading to more harborage points and difficult-to-clean equipment.

Due to modifications, this small product guide shown in Figure 1 now requires multiple tools to disassemble it for cleaning.

Figure 2 shows a dough elevator redesigned to be easier to disassemble for cleaning. It can be fully disassembled with only one tool in only a few minutes, providing full access to all the parts to the sanitor or to the operator during a changeover.

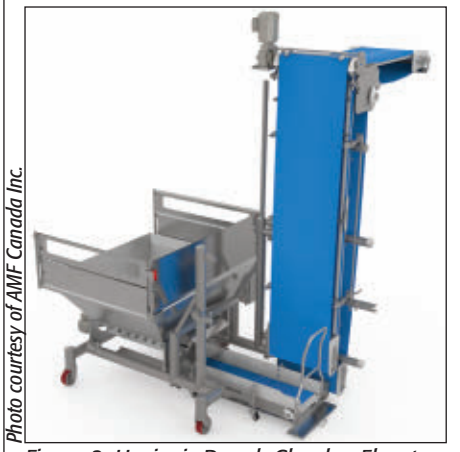

Photo courtesy of AMF Canada Inc.

Figure 2. Hygienic Dough Chunker Elevator

Some bakery OEMs invested resources into making their equipment truly easier to clean. However, we need to remember that some pieces of equipment have not gone through the same process and application of "hygienic" models and are nothing more than existing versions fabricated using stainless steel. They may be shinier, but they are still challenging to clean.

For legacy equipment, using a tool such as the GMA equipment design checklist or simply talking with the sanitors and maintenance technicians could go a long way toward making small modifications that could help greatly. Always think about the first concept: "*If you can't see it, you can't clean it or inspect it!*" Are there unnecessary parts or complex assemblies that could be simplified to make the equipment easier to clean?

Sanitation Processes

From a sanitation perspective, there are a number of advancements being made, but the industry still diverges in some areas, for example, run-time verification, sanitation method verification, and environmental monitoring.

Depending on the run time, the required cleaning frequency and the number of production breaks may need to be validated, because as mentioned earlier, there is an increased level of awareness when it comes to potential for toxin-producing microorganisms to grow in some dough/batter that will not be destroyed by the oven. Other scenarios that would require run-time validation include the application of slurry prebaked, for example, egg slurry, dairy slurry, etc., that could allow for microbial growth, especially if the slurry is recirculated and not kept refrigerated. Some bakeries are aware of the risk of applying an egg solution to the surface of products such as croissant bread to provide a shine to the baked product, but others have not identified this as a risk. Unless the slurry is formulated to prevent microbial growth, microbes may grow and contaminate the product. It is important for processors to understand the growth rate and clean the slurry system before it becomes a risk.

Similarly, while running a bread line for a week may not introduce hazards, other products may be more susceptible to microbial growth, and their run times may need to be validated. For example, a line making decorated cakes with whipped cream should probably be cleaned more frequently than once a week.

The approach to cleaning evolved to be more rigorous and better defined. Most processors are familiar with the seven steps of dry or wet cleaning. An example of the seven steps of dry cleaning is provided in Figure 3. The decision between dry and wet cleaning is driven by a few factors, such as the type of products, the presence of drains, the design of the equipment, and the infrastructure.

If a facility does not have drains, attempting to clean some of the equipment using wet cleaning methods such

as foaming and rinses would be more difficult, as the water will need to be directed and pumped somewhere to be removed. While it may seem to be faster to clean a piece of equipment such as a mixer using a wet cleaning method, without the drains, the time and effort that will be required to manage the water may exceed what would be required to perform a modified wet cleaning. The latter can be described as performing an effective and thorough removal of gross soils and then using a controlled amount of water–for example, using a bucket and brush or wipe–to remove product buildup.

Some equipment cannot be wet-cleaned, mostly because it can trap water, has electrical components that can be damaged by water, or is made of materials that can corrode. Too often, we still see bakeries wet-cleaning their cloth belts. These belts act like a sponge and will trap water; mold will grow on the surface of the framework or table supporting the cloth belt and the cloth belt itself. There are two options: implementing a dry-cleaning method or replacing the cloth belt with a monolithic belt.

Cloth belts also present a risk for extraneous materials: If they are not well maintained or their motion is not tracked correctly, they will fray on the edges, thus increasing the likelihood of having threads in the finished product. Another type of equipment susceptible to trapping water is ambient spirals that may not be allowed to dry after cleaning when low-moisture products are being produced.

Selecting wet cleaning for equipment and infrastructure that is not designed to be wet-cleaned may introduce not only microbiological risk but also extraneous matter by corroding surfaces that will rust or causing painted surfaces to flake.

Following two recalls related to *Salmonella* in dry breakfast cereals, Malt-O-Meal promoted a "war on water" within their facilities that covered many aspects to reduce the presence of water from the production environment. More recently, Karl Thorson of General Mills promoted an order of preference for cleaning dry facilities. His continuum ranges from: using dedicated equipment to minimize cleaning > push/flush > dry clean > dry clean with chemicals > clean in place > controlled wet cleaning out of place (part washer) > assisted cleaning system > controlled wet cleaning in place > flood cleaning. While this is not a statistically valid study, our experience tells us that performing an effective removal of gross soils through dry cleaning and minimizing the use of water reduces the number of *Listeria*/*Salmonella* positives in the environment, and pests, such as flour beetles, are less commonly observed. So, while the plant may not look "as clean" when only dry cleaning or modified dry-cleaning methods are used, indicators may show that the risks are lower.

Now, using dry-cleaning methods does not mean that you bring in compressed-air hoses and begin blowing dust around. The intent of dry cleaning is to remove soil, not just displace it. Some compressed air can be used in a controlled manner as a detail cleaning step after gross soils have been eliminated to remove soil in otherwise difficult-to-access equipment and only when other cleaning tools, such as vacuums, are not successful.

As pointed out by Thorson, it might be possible to:

- Perform dry cleaning on product contact surfaces using product push/flush by using an inexpensive but abrasive ingredient like salt or a "dummy" product such as a partial dough without the expensive ingredients to remove product from equipment
- Perform dry cleaning without introducing moisture by using tools such as scrapers, brushes, and vacuums
- Perform a modified dry clean by using some chemicals, such as an alcohol-based sanitizer and wipes to help remove soil from surfaces, or a limited amount of cleaning/sanitizer solution in a bucket with wipes or brushes to remove soils

Different cleaning methods such as dry steam or dry ice can be used to minimize the amount of moisture introduced during equipment cleaning. One should be cautious; these techniques move the soil from one part to another. Soils will need to be collected or picked up before operations begin.

All these options are available before a significant amount of moisture (water/cleaning solution) is added to the equipment/environment.

Coordinated Efforts Are Needed

Just as with many other product categories, there is an increased awareness of coordinating the sanitation activities of adjacent *(continued on page 66)*

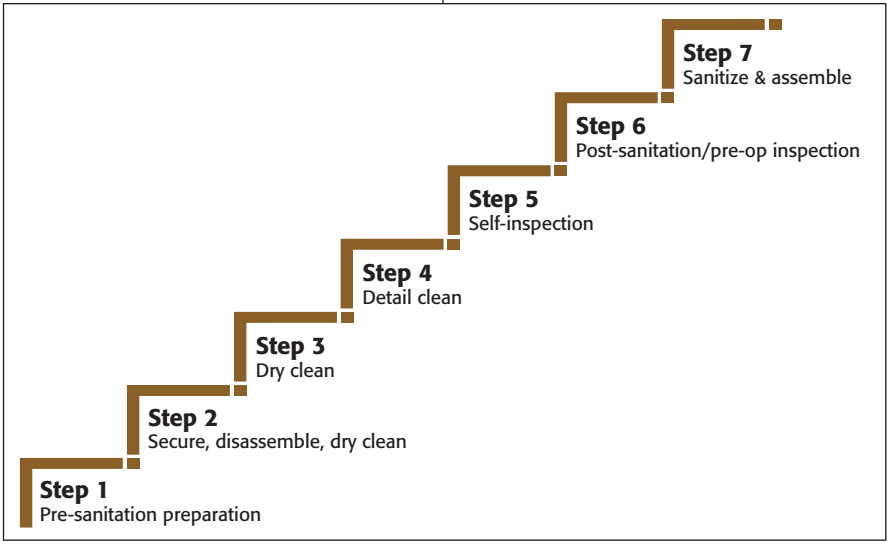

Figure 3. Diagram of the 7 Steps for Effective Dry Sanitation

By Nancy Dobmeier, CQA, CHA, and Balasubrahmanyam Kottapalli, Ph.D., CQE

Time Flies When Temperatures Rise

Risk assessment and management strategies for the control of toxin-forming bacteria in high-moisture matrices

Are there any steps in the processing of your food product where it is in a high-moisture state before baking, cooking, or freezing? Perhaps it is a batter or component of a finished product. Making microbiologically safe food does not rest solely on having a validated kill step. Even in systems that include a lethality step, food may cause illness or trigger a recall if manufacturing conditions allow or *could allow* toxin-producing microorganisms to grow to levels at which heat-stable toxin is formed.[1–12] The *Code of Federal Regulations*, 21 C.F.R. Part 117.8 (c) (3), states, "Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding."[13] During manufacturing, however, it is not always possible to hold components at refrigerated temperatures. Thus, to prevent foodborne illness or recalls, it is important to tailor residence time for high-moisture components or raw work in process (WIP) such as slurries, doughs, or blanched vegetables to the warmest temperature found in the matrix occurring before the kill step. This article will focus on the risk assessment and management strategies for minimizing the potential for growth of undesirable microorganisms leading to toxin production in a food matrix/manufacturing system.

Perform a Risk Assessment

Determine whether the matrix and conditions meet the criteria necessitating time/temperature control. Ingredients, pH, water activity, salt concentration, and temperature can impact the potential for the growth of microorganisms to levels of concern in high-moisture matrices.[14,15] Buildup or residual material can present a risk when a continuous batching process is used by allowing greater time in these areas for microbial growth. These factors need to be considered when conducting a risk assessment to assist in determining allowable residence times, hold times, or time between cleanings.

1. Matrix parameters

If the water activity of the food/ingredient matrix under consideration is less than 0.85, it would not be considered "high moisture."[16] For materials with a water activity of 0.85 or greater:

- Determine pH. Is the pH greater than 4.0 and less than 9.8? If the answer is yes, continue.
- Determine the percentage of water-phase salt (WPS). Is the maximum percentage WPS of the material less than 10? If the answer is yes, then time/temperature controls are probably necessary for the high-moisture slurry during manufacturing. Continue with the risk assessment.

The minimum pH for *Staphylococcus aureus* or *Bacillus cereus* growth is 4.0 or 4.3, respectively. *S. aureus* will not produce toxin, and *B. cereus* will not grow if the WPS is 10 percent or greater.[14] Therefore, if the answer to either of these questions is "no," then the assessment may be discontinued.

2. Organisms of concern

As part of your Hazard Analysis, consider available scientific literature to understand specific microbiological hazards associated with incoming ingredients. Engage a subject-matter expert as necessary. Although it might

not be associated with any ingredients, *S. aureus* must still be considered since humans are known carriers of this microorganism.[17] Examples of steps where direct or indirect inoculation of product may occur are reassembly of equipment after sanitation, weighing of ingredients, or tasks conducted near or over open equipment.

Consider in the risk assessment competing microflora such as yeast or lactic acid bacteria either added as an ingredient or naturally occurring. If at adequate levels in the food, these microorganisms may suppress the growth of *S. aureus* or *B. cereus*.[18,19] A lab study is essential to confirm growth suppression and should be verified at some frequency, especially when there is a change to the process or formulation. If the competitive microorganisms are indigenous to an ingredient or added as part of the formulation, inhibition also should be confirmed when there is a change in ingredient supplier because indigenous microflora and strain characteristics can differ, depending on the source of the ingredient.

3. Temperature

Review temperatures (if there is monitoring, continuous or otherwise) or collect temperatures of the material in the flow. Identify areas or process steps (including known or potential hang-up points) where product is held at temperatures that would support the growth of microorganisms.

4. Potential growth and toxin production

If the temperature of your material or WIP at its warmest area in the system can be maintained at temperatures below 50 °F, then toxin formation by *S. aureus* is not likely.[14] If temperatures cannot be controlled below 50 °F, then use predictive pathogen growth modeling programs such as ComBase Predictor or the U.S. Department of Agriculture's Pathogen Modeling Program to help assess risk over the temperature range of concern. Use worst-case scenarios for your product parameters and temperature. If predictive modeling (typically based on broth studies) indicates that growth of these organisms exceeds the food safety limit at which toxin production is typically initiated (e.g., 10^5 CFU/g), then an inoculated challenge study using your specific matrix may be needed to define the potential for growth of the target organism over time at various temperatures. These results can help determine acceptable residence times at specific temperatures during manufacturing. Once modeling or a challenge study is complete, a table may be constructed with temperature ranges and the allowable hold time for those ranges. An example is illustrated in Table 1. Findings from published literature may be useful to aid in the design of control limits for your process. However, caution must be exercised to ensure that matrix parameters and pro-

Temperature of slurry in the tank or around hang-up points	Rinse-down (or other equivalent sanitation measures) of the hang-up points must be performed within:
46–50 °F	72 hours
51–55 °F	46 hours
56–60 °F	27 hours
61–65 °F	17 hours
66–70 °F	12 hours
71–75 °F	8 hours
76–80 °F	6 hours
81–85 °F	7 hours
86–90 °F	4 hours
91–95 °F	3 hours
> 96 °F	< 2 hours

Table 1. Maximum Allowable Residence Time for Slurry Based on Temperature
Note: The above example is provided for illustration purposes only. These temperatures and times may vary based on the intrinsic and extrinsic properties of the evaluated matrix and manufacturing conditions. Manufacturing facilities must perform a Hazard Analysis specific to their matrix and identify appropriate preventive controls.

cess parameters described in the literature apply to your specific product.

5. Document

Document your findings in the food safety plan. If risks do exist, construct a strategy for mitigation and management. An example can be found in Table 2. Develop procedures and training for personnel.

Management Strategies

The following are example strategies for managing the potential risk of pathogenic microorganism growth and subsequent toxin production. Strategies may vary with the type of matrix, sanitary design of the equipment, manufacturing practices, sanitation frequency, or other factors. Work with an expert microbiologist to formulate an effective control strategy tailored to your manufacturing facility. Examples include:

1. Control of residence time

Establish allowable maximum residence time based on the highest occurring temperature in the matrix. If the temperature of the material at its warmest area in the system can be maintained at 50 °F or lower, then residence time will most likely depend on other factors such as quality. Do not allow the high-moisture matrix to remain at a temperature longer than results from modeling or a challenge study dictate. Remove material from production before that occurs. If the process for the matrix is continuous, then the maximum length of time between full sanitation cycles will be determined by the results of modeling or the challenge study unless interdictive cleaning is implemented.

2. Sanitation and interdictive cleaning

Interdictive cleaning is a step that may be taken between full sanitation cycles. It refers to simple scraping to remove product from the specific locations identified as hang-up points in the initial risk assessment. A food manufacturer needs to tailor sanitation practices to the holding time allowed for high-moisture WIP based on the warmest temperature of the material. So that growth cannot reach the food safety limit for toxin production (e.g.,

Slurry Temperature Control
Hazard: Growth of *B. cereus* to levels where enterotoxin may be produced. (Water activity of slurry is > 0.95 and pH is 6.0.)
Parameters for control: During normal manufacturing, slurry temperature is maintained below 65 °F and a maximum time of less than 17 hours between interdictive cleanings is allowed. When downtime occurs, temperatures are monitored every 30 minutes and compared with Table 1 to determine allowable hold time until such time that slurry must be destroyed and interdictive cleaning employed.
Monitoring: What: Holding tank temperatures How: Programmable logic controller probes When: Continuously Who: SPC system
Corrective actions in the event of monitoring failure: All product produced back to the start of the deviation shall be restricted and placed on HOLD for a food safety evaluation OR product is destroyed OR product is diverted to nonfood use. Appropriate Sanitation Standard Operating Procedures shall be implemented.
Record keeping: Printouts, charts, or readings from continuous temperature-recording devices AND record of visual checks of recorded data are maintained per the company policy.
Verification: Temperatures are collected from temperature-reading/recording devices and compared/calibrated daily to a National Institute of Standards-certified thermometer using accepted procedures. All records are reviewed within 1 week to ensure completeness and to ensure that any critical-limit deviations were appropriately addressed.
Validation/reference: Based on Pathogen Modeling Program modeling.

Table 2. Slurry Management Strategy for the Control of B. cereus
Note: The above example is provided for illustration purposes only. Manufacturing facilities must perform a Hazard Analysis specific to their matrix and identify appropriate preventive controls. Qualified individuals assigned to preventive controls monitoring, corrective actions, verification, and record-keeping activities must receive appropriate training for the tasks.

10^5 or 5 log CFU/g), interdictive cleaning should occur at a time point where theoretical growth is less than the theoretical level for toxin production for the organism of concern (e.g., 5.0×10^4 or 4.6 log CFU/g). If surfaces can be rinsed, the equipment must be visibly clean after rinsing. Determine whether growth can occur in dried-on product by collecting a sample and testing the water activity. If it is less than 0.85, toxin production cannot occur.

3. Equipment modification

Partner with your engineering department to determine whether modifications can be made to the equipment that holds the high-moisture material so that it is shielded from hot temperatures or jacketed to maintain reduced temperatures. An alternative is to cool the room and maintain temperatures that slow the growth of target microorganisms. While equipment or room modification might sound like the easiest approach, it may prove difficult and expensive. Unintended outcomes may occur such as condensation or increased viscosity, leading to reduction in flowability. If you are installing a new line, it is recommended to use information from microbial growth modeling or a challenge study to optimize the food safety design of the equipment, room, and run schedules.

4. Foundational food safety programs

Foundational food safety programs probably will not be the sole controls for preventing the presence or growth of *B. cereus* or *S. aureus*, but they are important components of a food safety plan. Examples of foundational elements to consider are:

a. *Ingredients.* Build stringent ingredient specification and supplier verification programs. Set the specifications or target values for microorganisms of concern as low as reasonably possible to help allow the greatest run time. All certificates of analysis of incoming ingredients must be verified at the plant and any deviations escalated.

b. *Good Manufacturing Practices (GMPs).* Ensure that the manufacturing facility's food safety plan includes GMP requirements for employees when they are handling ingredients or slurries. These GMPs should be used to prevent the opportunity for inoculation by human carriers of *S. aureus* (e.g., wearing of gloves, face masks). In addition to line employees, these GMPs should apply to all employees in the plant, including personnel from maintenance, sanitation, quality control, and management.

5. Unplanned downtime

Care must also be taken when unplanned downtime occurs to ensure that growth in the matrix does not approach the limits for food safety. When a line goes idle, the temperature from the warmest area of idle WIP must be measured and recorded throughout the idle time. A previously constructed table based on modeling or a challenge study will facilitate efficient decision making regarding when the material must be destroyed and equipment rinsed or cleaned. Alternatively, modeling that reflects real-time progression in temperature may be conducted to determine disposition of material using the "dynamic" option in ComBase Predictor.

Conclusion

Recalls or outbreaks relating to *S. aureus* and *B. cereus* contamination of food are of major public health concern, specifically due to their ability to produce heat-stable toxins that cause foodborne illness. Once formed, these heat-stable toxins cannot be eliminated with currently available chemical or physical decontamination treatments. Hence, controlling the residence times of temperature-dependent, high-moisture matrices during manufacturing becomes an important consideration for food processors. This article proposes a risk assessment framework and several management strategies for minimizing the potential for growth of undesirable microorganisms leading to toxin production in a food matrix/manufacturing system. Follow- *(continued on page 64)*

By Bob Ferguson

Processors Increasingly Turning to Testing for Allergen Control

FSMA regulations put allergens in the spotlight

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.*

In our last Food Safety Insights column, we looked at the progress food processors are making in their efforts to comply with the Food Safety Modernization Act (FSMA). While we found that most processors report that they are indeed in compliance or close to where they need to be, one of the issues that they reported that is still a challenge—especially in their supply chain—and causing them to make changes in their program is control of allergens. So, this article will focus on allergen control and what processors are doing.

Recall from our previous article that the data for this study are from the survey that we completed in August 2018, in which we asked 280 processors from around the world what steps they are taking to improve their allergen control programs.

In this sample, roughly 30 percent of the processors in the U.S./Canada reported that efforts to comply with FSMA have significantly changed the way they test or control for allergens. For those suppliers outside the U.S./Canada, 38 percent reported that they had made significant changes.

The data indicate that processors are making preventive efforts to maintain or improve the performance of their programs rather than as a response to major incidents or other remedial efforts. I mention this because 95.5 percent of the respondents reported that they had not had a recall due to allergens. This does not mean that they have had no problems related to allergens, and they certainly may have faced situations that caused them to dispose of product or conduct additional cleaning processes or numerous other responses where their operations may have been impacted at significant cost. From the data and the comments we heard in our interviews, however, their programs appear to have caught major issues, at least before they rose to the level of a recall.

Why Some Processors Don't Test

When asked what changes processors are making, the most frequent answer, accounting for one-third of the responses, was "more testing" (Figure 1). This was balanced by another one-third who reported that they conducted no testing at all because they rely on data from their suppliers, they have a product with no known allergens, or their product itself is a known allergen (e.g., seafood and nuts being the most commonly mentioned). Outside of testing, the next most common answers for changes that had been made were "improved product segregation" processes and "updated documentation and labeling." Others mentioned that they had updated their process validations, including changing their definitions of "clean."

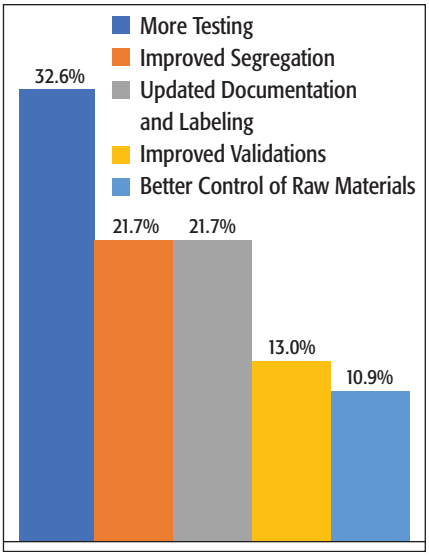

Figure 1. Has FSMA changed the way that you test or control for allergens? (% of respondents indicating a top concern)

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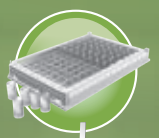

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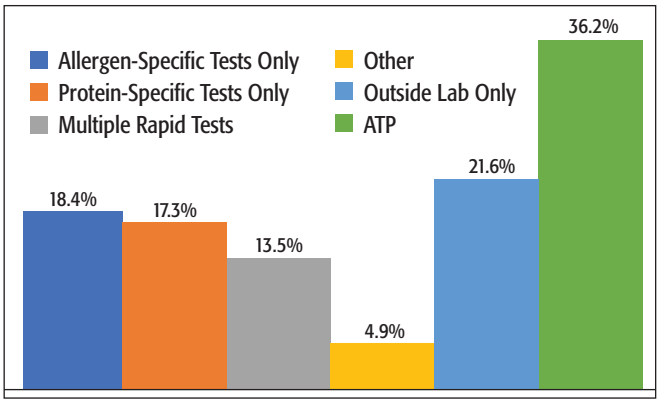

Figure 2. How do you test for allergens? (% of respondents indicating a top concern; percentages add up to more than 100% due to the use of multiple methods)

We asked about the types of testing processors are doing. Of those reporting that they were using in-plant, rapid methods, 18.4 percent reported using allergen-specific tests only, 17.3 percent reported using protein-specific tests only, and 13.5 percent reported that they use both types of these rapid tests (Figure 2). When asked about the use of outside commercial labs, 21.6 percent said they exclusively send their allergen samples out for analysis, whereas nearly one-half said they send at least some samples to an outside lab. Close to 40 percent also reported using ATP specifically as part of their allergen control program.

We also asked what products or services processors wanted to see to improve their allergen control programs. With the number of respondents reporting that testing was a concern and that they expected to increase their volume of testing, it was not surprising that the top response mentioned was related to test methods: 36.9 percent said they would like to see "more specific and faster" allergen test methods. This was the favorite answer by a ratio of more than 5 to 1 over the next answers, which included "better training programs" and "better color-coding and labeling tools" (Figure 3).

Processor Wish List

In the test category, processors mentioned that they would like to have a test that "tests for all eight major allergens in one test" (especially U.S. processors). Others mentioned a need for "tests for more of the rare allergens, outside the Big

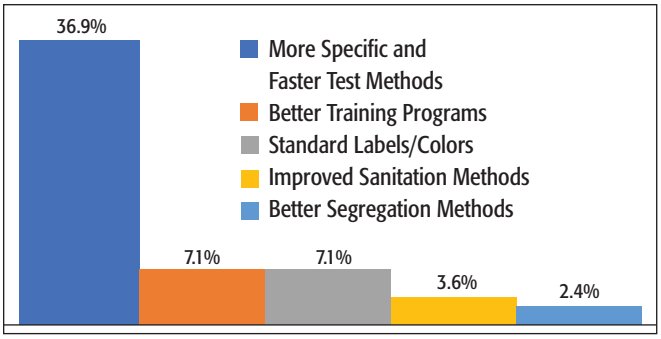

Figure 3. What would you like to see that would improve your allergen testing program? (% of respondents indicating a top concern)

8 or Big 11 [including Canada], like coconut and other tree nuts." One snack food producer very directly stated, "Plant labs are in need of tree nut-specific tests." Another processor mentioned that they had to develop their own in-house test for an uncommon allergen because a commercial test was not available.

This is clearly an opportunity for diagnostic companies focusing on this part of the rapid testing market. Referring to the data in this survey, and using additional unpublished data that we have collected, we estimate that the worldwide market for rapid test products for use in allergen programs (allergen and protein tests, excluding ATP tests) exceeds $100 million. By test volume and market value, the market is skewed somewhat toward tests that are allergen specific. Although the numbers of processors who use each type of test (or both) are comparable, processors report using nearly twice as many allergen-specific tests on a weekly basis as protein tests. Because of this, our estimates place the value of the market for allergen-specific tests in the 60–65 percent range of the total market. But there is also a clear demand for better, faster, and more specific tests, creating growth potential in this market and an opportunity for those diagnostic companies that can respond.

In other categories outside of testing, several asked for better dust control and containment measures, especially to control cross-contamination via dust on employees. Rolling this request together with their testing needs, several asked for air control with integrated allergen-detection systems. Other similar requests for electronic-based allergen detection and alert systems were also common.

Other processors mentioned that standardization of other tools, such as standardized color-coding systems (e.g., assigning specific colors to each of the Big 8 allergens), could be used on tools and materials, as well as on plant forms and paperwork, and would be useful, especially when trying to align their supply chains. We also noticed a demand for better training systems and tools. People mentioned that cross-contamination from employees was a common problem, either from lack of adherence to segregation processes or, in what was described as even more frustrating, employees bringing allergens into the plant from the outside, especially in their lunches. This observation aligns well with what we reported in our February/March 2018 column, when nearly 40 percent of processors reported that employee training and compliance was a "program weakness."

From our conversations with processors, this is an area that will only continue to require more focus. As we saw in our last article, some of this focus will be directed at better control of their supply chains. But we also see that testing will increase, as will internal control of cross-contamination through processes and the need for better employee compliance. ■

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By Jory D. Lange Jr., Esq., and Candess Zona-Mendola

Walking on Eggshells: Do You Know the Risks?

Egg safety begins with the chicken farmer

Tap. Tap. Crack.

It's the early morning sound that, together with the coffee pot's gurgling, makes us immediately hungry. The egg is the ultimate American food staple. Along with bread, milk, and water, it's one of the first foods to sell out in grocery stores during an extreme weather warning. And there is no question about it: With an impressive range of vitamins, minerals, proteins, and good fats, eggs are nature's perfect food.

Despite Americans' familiarity with eggs, many do not know their secret: Eggs are one of the most dangerous foods that we eat. So dangerous that in the last few years alone, hundreds of millions of eggs have had to be recalled. Why all the fuss? Because all too often, those innocent-looking eggs that we buy in the store are contaminated with *Salmonella*.

And *Salmonella* is not just trapped inside the eggs. *Salmonella* can also be on the egg's shell. When you buy eggs at the grocery store, do you open the carton to make sure they aren't cracked? Most people do. Do you ever touch the eggs? Millions of Americans do each day. Few Americans realize that those innocent-looking eggshells they have just touched may be contaminated with *Salmonella*.

It All Starts with the Hen

It's dawn. A hen is sleeping in her community coop. Shafts of light from the rising sun peek through the holes of her coop, and she begins to stir. The hen lays an egg.

Thus begins the egg's epic journey to your plate.

It does not stay in the nest for long. As the hen moves about her nest and begins to peck at the feed brought to her on the conveyor belt, the egg slowly rolls down to its own conveyor belt. Along with the other eggs that have been laid that day, the egg gradually makes its way to a processing room.

The egg rolls from one belt to another as it continues through a series of sizing equipment. Next is another conveyor that takes it through a cleaning machine. The egg then is dumped into a water bath to continue the drying and candling process. Next, it is rolled back onto yet another conveyor belt to its next destination. As the egg begins to dry, a processing worker inspects the egg and its compadres, carefully removing any eggs that appear to be broken, malformed, or dirty, essentially any that have not already been removed during the candling process.

As the egg continues on its journey, it passes inspection and moves to the next part of the process: stamping and packaging. A special machine gently suctions the egg and others of its size into an appropriately sized egg carton. It is wrapped and placed in cold storage. From here, the egg could travel to any number of places. It may be distributed to the nearest grocery store. It may be loaded onto a truck and driven to another state. Or it may be exported to another country. Most likely, it will change hands at least three or four more times before arriving at its final destination, the breakfast plate.

But what does the egg's journey have to do with *Salmonella*?

Many Americans don't realize that from before the egg is even laid until the moment when the egg is packaged into its carton, there are repeated opportunities for the egg to become contaminated with *Salmonella*. And not just on

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the inside of the egg but on the shell, too.

Herein lies the problem. Egg safety begins with the chicken, or rather, the chicken farmer. In well-run egg farms, farmers are ever vigilant in identifying and then eliminating any possible routes of *Salmonella* contamination at each step in the egg's journey from hen to fork. But in poorly run egg farms, eggs may become contaminated during their journey. And if hens become infected with *Salmonella*, their eggs may be contaminated with *Salmonella* even before they are laid.

> "…all too often, those innocent-looking eggs that we buy in the store are contaminated with *Salmonella*."

How *Salmonella* Can Get into (and onto) Eggs

There is nothing new in the link between *Salmonella* and eggs. When we were children and our mothers told us not to eat raw cookie dough, they were trying to protect us from the danger of *Salmonella* hidden inside eggs.

But what is the real danger? How can something as small as an egg send someone to the hospital, let alone cause a multi-state outbreak?

There are four main ways that eggs become contaminated:

1. Biosecurity failures that introduce *Salmonella* into chicken coops
2. Pest infestations
3. Lack of proper cleaning and sanitization procedures
4. Improper holding temperatures

Let's take a look at each of these factors individually.

Biosecurity Failures

Infected chickens may not show any signs of *Salmonella* infection. In fact, they rarely do because certain species of *Salmonella* do not make chickens sick. That is why it is important for egg producers to routinely test their chickens–especially because *Salmonella* infections in the ovaries can transfer into the egg.

Chickens are messy. They are animals, after all. Unlike us humans (and the more pampered house cats we know), chickens really do not care too much about cleanliness, especially where they walk, eat, or do the other things that nature intends them to do. This means that chickens will pick up any pathogens they encounter in their environment. If an animal, for instance, gets into a coop and exposes the coop to bacteria, the entire coop may become infected. If an infected chicken is introduced to the coop, the infection can spread. This is why it is so important to keep coops clean and free of any potential contaminants.

Pest Infestations

Rodents and flies are not just annoying, but like the spread of plague by fleas on rats, they also cause a huge problem when it comes to pathogens. Again, an entire coop of chickens can become infected through just a cluster of flies. Pests also can leave their own natural elements behind, creating another opportunity for more bacteria to colonize.

Improper Cleaning and Sanitization

The egg's journey from hen to fork is littered with opportunities for bacterial contamination. As with any food processing facility, proper cleaning and sanitation are crucial. All the more reason why it is not surprising when *Salmonella* outbreak investigations unearth basic breakdowns in cleaning and sanitation programs. In this year's Rose Acre Farm outbreak, U.S. Food and Drug Administration (FDA) inspectors observed that the facility's cleaning procedures were "not being implemented by management and followed by sanitation employees," that maintenance and sanitation employees were placing food contact equipment "onto floor, pallets, and equipment that was visibly dirty with accumulated grime and food debris, before placing the equipment into service," and that "production and maintenance employees were observed touching non-food contact surfaces (i.e., face, hair, intergluteal cleft, production equipment with accumulated grime and food debris, floor, boxes, trash cans, inedible transport cans) and then touch[ing] shell eggs and food contact surfaces…"[1]

Improper Holding Temperatures

Say it with us now: "Keep hot foods hot and cold foods cold." You know the mantra. For those of us in the food safety field, it is ingrained in our brains. We are pretty sure most of us say it over and over during dinner parties when we have that one friend who just has to push the limits of the 2-hour rule.

But when it comes to eggs, proper holding temperatures are more than just a spoilage concern. Holding temperatures are an exposure concern, too. We all assume that eggs are pretty well protected, that their shell is their armor. People often assume that the egg inside will always be OK, despite any environmental exposures the shell may endure.

Dead wrong. The egg's shell is porous. Bring yourself back to your ninth-grade biology class for a moment. Do you remember learning about cell structure and a little thing called osmosis? Well, eggs do that. When a cold egg is left out at room temperature, the water inside the egg will cause the egg to sweat–or rather transfer to the outside of the egg. This means that whatever pathogens may be lurking on the outside of the egg can do the reverse and pass through the shell into the inside of the egg. And what do we all know about pathogens? They like to grow and colonize. Something as minor as leaving an egg out at room temperature can lead to creating one's own food poisoning bomb.

Salmonella Outbreaks

Time and again, *Salmonella* outbreak investigations reveal basic breakdowns in biosecurity, pest control, cleaning and sanitation, and holding temperatures. When it comes to *Salmonella* egg

outbreaks, there really is nothing new under the sun.

These failures are why we repeatedly see outbreaks linked to eggs. The link between *Salmonella* and eggs is not new. We knew about it back in 1987,[2] when 500 people became sick from eating raw eggs that had become contaminated by *Salmonella* transmission from the chicken's ovary to the egg. We saw these same types of food safety violations during the Wright County Egg/DeCoster Farms outbreak in 2010– where FDA inspectors arrived to discover chicken coops teeming with flies, maggots, scurrying rodents, and overflowing manure pits. Wild birds were allowed free run of the coops, infecting laying chickens. Chickens that were obviously sick were allowed to mingle with healthy birds. And that is just a little about the laundry list of food safety violations in that outbreak. Investigations later revealed that these critical food safety violations went back decades.

> "As the egg-producing industry moves toward a cage-free future, many... food safety advocates...are wondering what this ...will mean for food safety..."

But that was 8 years ago; surely the egg industry has learned from its mistakes. Surely after the DeCoster catastrophe, egg producers are always doing the right thing. Some are. But others still are not.

We don't have to look any further than the 2016 Good Earth Egg outbreak and this year's Rose Acre Farms outbreak to see that there is still a problem. Good Earth Egg failed to test their hens for *Salmonella*. Their biosecurity measures, or rather lack thereof, failed. Equipment was moved from the coops to the processing areas without first sanitizing it. Cleaning and disinfection systems failed. And don't even get us started on the rodent infestation.

As for Rose Acre Farms, this latest tale of egg woe is like comparing *Romeo and Juliet* to Pyramus and Thisbe. Same story, different names. FDA's investigation revealed pest infestations: "unacceptable rodent activity within a poultry house" and "flying insects throughout the egg processing facility…landing on food, food contact surfaces, and food production equipment"; biosecurity failures: "condensation dripping from the ceiling, pipes, and down walls, onto production equipment" (remember Peanut Corporation of American's leaking ceiling?); and improper cleaning and sanitation: "insanitary conditions and poor employee practices observed in the egg processing facility that create an environment that allows for the harborage, proliferation, and spread of filth and pathogens throughout the facility…"[1] This year's *Salmonella* egg outbreak (and ensuing recall of 207 million eggs) is just the latest of its kind. It's a tale as old as time.

We are seeing the same violations lead to *Salmonella* outbreaks over and over. It makes you wonder: Do over a billion eggs need to be recalled and thousands more people become sick before the egg industry wakes up and follows the rules?

A Cage-Free Future

As the egg-producing industry moves toward a cage-free future, many consumers, regulators, producers, and even food safety advocates like us are wondering what this change will mean for food safety and *Salmonella*.

We are seeing some mixed emotions.

At one end of the spectrum, some egg producers have claimed that going cage-free will open up their chicken flocks to a new laundry list of environmental exposures and potentially lead to a greater risk of illness. But that assumes that *cage-free* means getting to go outside like free-range chickens. It doesn't. In most cases, *cage-free* means just that. No cages. The birds are still cooped up in an indoor coop. They are still packed together. It is like having a seat at your favorite concert hall versus the same concert hall being standing room only. When it rains, there's still a roof over your head.

Those in favor of the shift cite research showing cage-free production practices improve food safety, specifically studies like the 2009 Huneau-Salaün study[3] (which concluded that the prevalence of *Salmonella* was found to be higher in caged flocks) and the 2015 Penn State meta-analysis[4] (which concluded cage housing for chickens increases the risk of *Salmonella* contamination). A 2010 British paper went on to essentially say the same thing–that eggs from caged hens had 7.7 times greater odds of harboring *Salmonella* bacteria than eggs from noncaged hens.[5]

There are others in the debate who do not necessarily care either way, because they believe that a cage-free shift will not do anything to benefit food safety but will rather appease the customer with a (perhaps misleading) sense that their eggs are now more humanely produced.

Will going cage-free allow for a more sterile environment? Or will it just make things dirtier? Will environmental conditions for laying hens actually be better? Will going cage-free mean more or fewer antibiotics? Or will it have no effect whatsoever? We will just have to see.

The critical question for egg-producing corporations will be: How strong is their food safety culture? Are corporations willing to pay for necessary testing? Are they willing to invest in quality equipment and training of their employees on food safety practices? With a huge investment in new equipment and facilities to allow for cage-free hens, coupled with a concern that the consumer market won't pay the high premium prices for eggs, will more corners be cut? Will sanitization and cleaning practices *(continued on page 63)*

Managing Food Safety Risk in a Foreign Supplier Verification Program

By Dr. John W. Raede

My introduction to a foreign supplier verification program (FSVP) was in 2013 by way of a coworker, Tim Jackson, Ph.D., who said, "Hey, Raede, your world is about to get more interesting" as he chuckled and walked away. At the time, I was working in a global supply chain quality management capacity. I did quite a bit of international travel to perform focused risk assessments, creating business relationships, building trust, and eliminating process variation. My worldview was all about walking the factory floor, watching processes, collecting data, analyzing, identifying issues, creating collaborative corrective actions, implementing them, and validating if they accomplished what we intended. Boom—done. Little did I know how prophetic Tim's words would be 5 years later when an opportunity presented itself that I knew I had to pursue.

I had been searching for a challenging, faster-paced environment that required my experience and process knowledge in an expanded role. In March of 2018, I came to an agreement with an importer of record (IOR) that supplies an array of imported and domestic food ingredients for the U.S. industrial market. I had the pleasure of working with this family firm for 15 years in my previous role because they were one of my suppliers. Switching from a corporate-based "silo" structure to a "many hats" format was tough enough, and add to that the challenge of working from a remote location with a 3-hour time difference. The FSVP was in the forefront of this position, and I had to jump in and gain an understanding immediately. Fortunately for me, the program was set up by a very competent and capable individual, Breanna Neff. She was a recent graduate of the Cornell University Food Science Department and had to start from scratch to build the program.

Importance of the Document Exchange Process

Document management was not in my circle of responsibility in my previous role. I really had no idea of the volume of documents that were required at the time and what the future regulatory requirements would eventually generate. Once in, I began to realize quickly how providing documentation in a timely manner is a critical component of the customer service capability for this type of organization. Especially in a new ingredient/product introduction that is on a tight implementation schedule. You do not want to be the reason a potential piece of business is lost in any-size organization.

The technical folks need the backup documents to begin the process, and if they are not received in a timely manner, the process comes to a halt. The goal should be to keep that process running smoothly and be considered as the best IOR to work with. The challenge is how to keep the updated version of the documents that have expiration dates (most are annual) available when requested.

> "Business is about relationships, and relationships are personal."

Document management services are becoming popular; there are two main choices in the marketplace to my knowledge. I'll let you do your own research to determine which is the best fit for your operation. If you are supplying to a large-scale operation, you are already engaged in the process with a supplier portal and receive the barrage of notification emails regarding expired and/or new document requests. There are least-cost options available that require a database-to-database transfer from your supplier to your customer, or the often more expensive "pass through" option.

Caution: Although a web-based system is an efficient method to control the document management portion of the FSVP, you must be careful not to lose the personal side of this operation. Numerous times, I receive document requests, turn them around quickly, and receive a sincere note back thanking me for the speed of the response. You cannot ignore the importance of that interaction. Remember, business is personal: It is all about relationships based on trust through verification.

Supplier Risk Assessments

I've always believed that the way we conduct ourselves in our professional life is basically how we are in our personal lives. If you like to travel, learn about different cultures, learn different languages, eat different foods, sleep in airports, continuously request documents, and send documents, you too can be an FSVP professional!

One of my favorite phrases is: "Everything I've experienced in my life has prepared me for the challenges I am facing today." It is a guiding principle that allows me to have the mental fortitude to walk into a situation with confidence, prepared to handle whatever will be encountered and be prepared for the next challenge.

I remember 25 years ago how I kept repeating that mantra the first time I disembarked the Boeing 747 in a country that required a business visa and generated personal safety warning documents from our in-house travel agents. Didn't know the language, culture, the airport, or even if our contact had arranged transportation. After receiving scrutinizing stares through the maze of customs agents, I received the stamps of approval on my passport and stepped into the cacophony of awaiting loved ones, vocal tour guides, and taxi services. Much to my delight, a gentleman was holding a piece of paper with my name on it, and after an awkward hug (from me to him), off we went.

The assessment went better than expected, the factory programs exceeded my expectations, and the translation challenge was minimal. The important factor that was recognized by all the parties involved was the development of a rapport. We dined together for lunch and dinner. We spoke of our families and shared similar experiences that narrowed the cultural differences. When I left, I knew I had connected with the managers, and they understood why I asked the questions I did, pushed for verification, and left them with a list of items to mitigate risk for our customers.

We were a company with one emerging brand that had a robust internal prevention program, and we needed to implement those risk-mitigation strategies in our supply chain. My boss at the time, Dale R. Rice (who is now Dale R. Rice, D.V.M.), coined a phrase, "Realistic specifications, rigidly enforced." He encouraged me to audit to the specification for each ingredient at the supplier locations. A thorough ingredient specification will cover the quality and food safety attributes important to the customer.

My previous experiences with implementing a supplier management program for a single brand and multiple product variations grew into multiple brands and select ingredient categories via an acquisition by a global corporation. I spent the subsequent years managing domestic and foreign supplier performance. This advancement over a period of 25 years increased supplier knowledge into currently implementing an FSVP for an IOR with approximately 70 products from an international supplier base.

An FSVP is not about performing multiple desk audits. While document and procedure review are crucial to a baseline understanding, the real learnings are derived from walking out to that factory floor and seeing it for yourself. You need to meet the line managers, line workers, maintenance technicians, and sanitation crew. They need to see what their customers look like and think about. Make it personal.

Business is about relationships, and relationships are personal. Your suppliers need to know you, understand what your concerns are, and what you can

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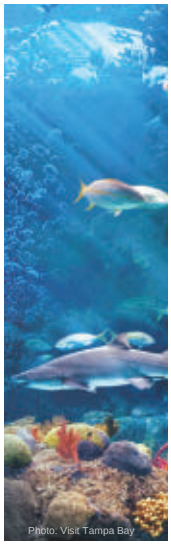
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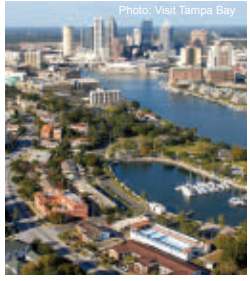
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do to help them. In my current role, we are focused on traveling to our suppliers' locations, having discussions with the factory professionals about practices and procedures, walking the factory floor, concluding the assessment with a closing discussion, and then enjoying a meal together while sharing our professional and personal experiences. Again, the personal side of business is important. I want my suppliers to care about our company, customers, and our customers' consumers.

The key to understanding any process is to deconstruct it and look at the parts individually while keeping in mind how they will all fit back together and function. Below is a list of the requirements of an FSVP and a summary of how I recommend addressing each one:

> "Your suppliers need to know you, understand what your concerns are, and what you can do to help them."

Use a qualified individual to develop an FSVP and perform FSVP activities: At a minimum, your designate should successfully complete FSVP training. Ms. Neff successfully completed a Preventive Controls-Qualified Individual (PCQI) training and an FSVP prior to setting up the structure, and I successfully completed the PCQI, PCQI Instructor, and FSVP courses.

Perform a Hazard Analysis that includes identifying known or reasonably foreseeable hazards associated with each type of food and determining whether they require a control: The intent of this item in the final rule is to ensure the IOR understands the risks associated with the ingredient they are bringing into the country. We prioritized the Hazard Analysis by product volume and lethality step control (supplier or customer), and performed an annual risk assessment focusing on preventive controls for biological, chemical, and physical hazards at our high-volume/high-risk suppliers.

Evaluate risks posed by the food and the performance of the foreign supplier: This requirement is ingredient-shipment specific. To quote President Ronald Reagan: "Trust but verify." Ask for supporting documents, go to the supplier's location, ask pointed questions, and gain a detailed understanding of your supplier's processes and procedures. We evaluate the process flowchart, Hazard Analysis document for the ingredient(s), validation studies for the lethality steps (if identified as a Critical Control Point), food safety plan, certificates of analysis per shipment, and supporting documents such as pesticide residue lab results.

Conduct appropriate supplier verification activities to provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented: This step is also focused on the validation of procedures and verification that the procedures are followed. Low-risk supplier verification activities may include reviewing updated third-party audits, conducting supplier meetings at trade shows, and reviewing corrective actions identified in the third-party audit and/or corrective actions for issues identified by our customers. Spending extra time on corrective actions is very important because it provides an insight into the management commitment of the supplier. I will address this further later.

Reevaluate the food and foreign supplier every 3 years: No matter the size and/or budget of your operation, you must request an updated Hazard Analysis and Critical Control Points (HACCP)/Hazard Analysis and Risk-Based Preventive Controls (HARPC) plan and risk assessment from your supply chain. We perform annual risk assessments at our high-volume suppliers. The benefits are twofold: First, we gain a visual perspective of process improvements from the previous year. Second, we strengthen the business-personal relationships with the management team by sharing meals and conversation. Document management systems come in handy when requesting the updated HACCP/HARPC risk assessments on a 3-year schedule.

Keys to Evaluating a Potential Supplier

A significant number of further processors retain their own in-house auditors or contract with third-party certification bodies. A recommendation is to conduct a targeted risk assessment for your customers to determine whether they want to invest the resources to move forward with the new ingredient on-boarding process. The purchasing, R&D, regulatory compliance, and food safety folks appreciate a heads-up, so to speak. Nobody wants to waste the substantial cost of sending an auditor to a location that will fail because of major deficiencies in their food safety plan.

In most cases, a certification body has audited the potential site, and a good idea is to carefully review the report. Another key component is a pre-site assessment, what some refer to as a desk audit. The HACCP flowchart for a review prior to each product is a standard item to have in hand when you are performing a desk audit and during the walk-through at the supplier location. It is your guide to what preventive controls have been identified as potential hazards by the factory management.

Risk Assessments

I have found that internal audits provide an insight into how a supplier manages their business. The internal audit identifies issues in the factory, and the corrective action completion data indicate the management commitment. Internal audits are a key component to an organization's ability to identify potential hazards, conditions that can cause disruptions in throughput, and situations that can create employee safety risk. A supplier that has a robust internal auditing program can prevent issues that may contribute to a system failure. The critical component to an internal auditing program is implementing an effective corrective action and then verifying the corrective action solved the issue.

Document requests are an integral part of the FSVP. In my experience, our customers keep track of their own document requirements via document control programs. I recommend you perform your own due diligence if you employ a system to manage the volume of requests your business generates.

Corrective Actions

One of the key items I look for is management commitment. This is one of the few things that may indicate whether you will have a successful relationship with the supplier. If the resources are not provided to pay for and train capable employees, provide them with the equipment and tools they need. In my experience, resources are required to pay/train/develop/retain competent managerial staff, and when the resources are not provided, the opportunities for failure increase significantly.

Management commitment is a leading indicator of the overall sustainability of the business. Capable managers do not stay with an organization that cannot support their initiatives. Factory managers require competent support staff to fulfill the goals and objectives of the business. If there is a solid team in place, there is normally an experienced, cordial, capable factory manager, general manager, and/or owner. A supplier with a capable and competent factory manager is less likely to have significant failures that cause food safety issues. An exceptional factory manager will conduct him- or herself the same with their staff, family, friends, vendors, and even waitstaff at restaurants. In my opinion, you can learn a substantial amount about someone from the manner in which they address people that are paid to provide a service. Have you ever had to disembark an airplane because of a mechanical issue? Personally, I am happy the leading indicators worked (found before disaster) and not the lagging indicators (reason for the disaster). More than once, I have stood in line after we have walked off the aircraft and the person in front of me is yelling at the gate agent, who did not ground the plane. To me, the person yelling is not an exceptional manager.

> "I want my suppliers to care about our company, customers, and our customers' consumers."

Site Assessments

An FSVP requires international travel, bottom line. If you don't like to travel,

then you should pick another occupation.

Personally, I really enjoy traveling. It is in my DNA. My aunt managed a traveling circus tent show. I would join them during the summer months, work in the concession stand, help with setup/takedown, and travel a portion of the country for 2 months. We had a set schedule of towns we would visit and set up for 2 days, perform six shows (three each day), take the tent down after the third show on the second day, and drive all night to the next town. It could be hectic when the weather didn't cooperate, the trucks broke down, or some of the crew would disappear on the way to the next location. The mantra was "The show must go on." The idea being, the folks paid their money and we must fulfill our obligation to provide the product, no matter the hardship.

Business travel to me isn't really that different from the circus days. Most of my assessments are scheduled by continent and require extensive scheduling. There are challenges to overcome, and unless I am completely incapacitated, I am going to show up. For example, while writing this article, I just completed the second week of a 5-week European trip performing risk assessments at 10 supplier manufacturing sites, involving nine hotels, six flights, and countless hours in a car or train.

> "Third-party audits play an important role in program and procedure verification."

In my opinion, to develop a successful FSVP, you must have a firm understanding of the products, process, people, and procedures. The more you are informed about the entire operation, the easier it becomes to speak or write cogently. Business is about personal relationships, and the stronger the relationship, the better the business. That means you must walk the factory floor. In the words of my good friend Chuck Regan: "If you're going to buy meat, you better have bloody boots, and if you're going to buy fish, you better stink."

Our customers require the current third-party audit certificate and the portion of the report that details the corrective actions. As an added component to the corrective action list, we request the status of the corrective actions and the validation study of the corrective actions' effectiveness. It's good to have corrective actions; however, they are not so good if they don't solve the issue. I highly recommend augmenting your suppliers' third-party audits with an additional annual visit to their manufacturing location(s) to perform a targeted risk assessment based on your customers' product specification(s).

Clarification: I am not saying that audits do not add value to the FSVP equation; however, as an FSVP practitioner, you *must* go to the location that produces the product you import and experience it for yourself.

Third-party audits play an important role in program and procedure verification. A skilled lead auditor can provide a valuable assessment of the overall effectiveness of the food safety plan, management commitment, and physical condition of the factory. I created a customized, risk-based assessment of each type of commodity we import, based on the customers' specifications and the inherent risk associated with the commodity type.

Meeting Customer Requirements

If you want to meet your customer's requirements, follow Dr. Rice's rule: "Realistic specifications, rigidly enforced." Let's expand on this. Sound easy? It can be when you work with a supplier that understands its process capability. This is where the relationship based on trust is essential. In my experience, we are presented with two specifications: what the customer requires and what the supplier can offer. Frequently, a supplier will generate a specification based on the parameters they consistently meet, and then they widen the upper and lower control limits to build in excess process variation. Understandable, and in some cases, the range is within the customer's specification. In some situations, the supplier may require assistance in understanding either how to achieve the customer's specification or why the parameters are in place. As an example, I had been working with European suppliers about *Listeria* spp. specification differences between their market and the U.S. market. Progress was slow until the European market recalls for individually quick-frozen (IQF) vegetables hit, and then the conversation changed from *why* should they comply to *how* can they comply.

There is a component within a food industry business that is not discussed to the extent I believe it should be. Food safety professionals play a vital role in the development of new business and maintenance of existing business, and should be recognized for doing so. I am truly blessed to work for an organization that recognizes the importance of my contribution to the business, and I reciprocate by doing everything I can to mitigate risk and promote the programs that we need to execute. While discussing what my role in the organization would entail, I proposed that we needed to make a bold statement that food safety was at the forefront of the operation. That is why my official title is Chief Food Safety Officer. We wanted our customers and suppliers to know what our focus is and how we would act upon it.

The Importance of Preventive Controls Validation

Food safety requirements are not getting easier because regulatory compliance and product liability are driving the demand for tighter product specifications. Processes that were partially ignored previously are coming under scrutiny for their contribution to risk mitigation. As the demand for reductions in pathogenic organisms increases, we are challenged to utilize existing processes to perform a lethality step that we

were not originally intended to.

As mentioned above, IQF frozen vegetables are in the forefront lately with a focus on validating the blanching process to achieve a 5-log reduction for *Listeria monocytogenes*. One segment of our customer base is focused solely on the blancher, and other customers will accept a combination of validated process steps to achieve a total 5-log reduction. We are still working through the details of the study. Understandably, our suppliers do not want to have studies performed that use product inoculated with *L. monocytogenes* in their facility and would rather use a surrogate organism. As the IOR, we have the responsibility to offer solutions that meet the customer specifications and are within the capability of the supplier. Not always the easiest move to execute; however, with a "quiver" of professional experts and associations from which to draw knowledge, we were able to offer salient solutions.

Some of our European suppliers did not want to blanch to a 5-log reduction because of the negative effects on the organoleptic characteristics that the increased time/temperature ratio has on the product. Our task was to help them understand the reasoning behind the requirement. In the U.S. market, the mindset is to "kill all of it!" We walked them through the validation study guidelines, certified laboratories that could perform the studies, and options that met their comfort levels.

Working with foreign suppliers to help them understand the U.S. domestic market can be a challenge. Creating a working relationship with the management team of the foreign supplier is a positive means to gain an understanding of each other's concerns and build trust.

Conclusion

If you've made it this far into the article, I want to thank you by leaving you with a brief summation of what I believe to be the pillars of a successful program. 1. Evaluate your suppliers' preventive controls thoroughly in their factory. Remember Chuck Regan's quote: "If you're going to buy meat, you better have bloody boots, and if you're going to buy fish, you better stink." 2. Your supplier must have the capability to manufacture to your customers' specifications. Remember the quote from Dale Rice, D.V.M.: "Realistic specifications, rigidly enforced." 3. Finally, you must challenge the validation studies of lethality steps and require pertinent process documentation. Remember the quote from Ronald Reagan: "Trust but verify." ■

Dr. John W. Raede *is the chief food safety officer for National Cortina, an importer of record for grass-fed beef, IQF vegetables, and edible oils. Dr. Raede specializes in food safety supply chain process improvement, risk mitigation, and foreign materials assessment and prevention.*

By Scott Wallin

Collaborative Spirit Drives Dairy's Food Safety Commitment

When Jeremy Travis chairs a meeting of the Innovation Center for U.S. Dairy's food safety committee, he is not surprised by the collaboration in the room. Travis, vice president of quality and technical services at Hilmar Cheese Co., has recently taken the reins of the 16-member food safety committee that develops and shares best practices to continuously improve and advance dairy processing and manufacturing procedures.

Continuous improvements seen in dairy processing

"It's a privilege to bring together experts from across the industry in a precompetitive forum," he says. "The research and work that the committee engages in would be difficult, if not impossible, for us to do as individual companies."

The Innovation Center for U.S. Dairy was created 10 years ago by Dairy Management Inc. (DMI), an organization that is funded by 40,000 U.S. dairy farmers and importers through the dairy checkoff. Dairy farmers pay 15 cents and dairy importers pay 7.5 cents for every hundred pounds of milk they sell or import into a generic dairy product promotion fund–the dairy checkoff–that DMI manages along with state and regional promotion groups. That money–with U.S. Department of Agriculture oversight–is used to fund programs aimed at promoting dairy consumption and protecting the good image of dairy farmers, dairy products, and the dairy industry.

Dairy farmer leadership of the checkoff saw an opportunity through the Innovation Center to unite the entire value chain around common goals and challenges, such as food safety, in a precompetitive setting.

Tim Stubbs, vice president of product research and food safety for DMI, manages the day-to-day priorities of the committee and its long-term goals. He sees the "convening power" of the Innovation Center up close.

"We have the top leaders and subject matter experts from across the dairy industry working together to solve problems and share solutions," Stubbs says. "It's like working with an all-star team."

Commitment to Food Safety

Sharpening dairy's food safety focus is not a new priority. In fact, the industry is built on decades of sharing through organizations such as the National Conference on Interstate Milk Shipments, 3-A Sanitary Standards Inc., and the International Association for Food Protection.

But the dairy industry also has seen the negative impact food safety issues have had on other categories, such as one of the worst in U.S. history involving the Peanut Corporation of America in 2008.

Dairy industry leaders, including Larry Jensen, who was president of Leprino Foods Company and chair of the Innovation Center at the time, and Mike Haddad, CEO and president of Schreiber Foods Inc. and current Innovation Center chair, wanted to make sure dairy heightened its food safety commitment as a result.

Committee member Edith Wilkin, vice president of food safety for Leprino, recalls Jensen saying the dairy industry needed to set aside its competitive interests and tackle food safety as a collective category. Jensen and Haddad felt strongly that food safety should never be used by a company as a competitive advantage and that a significant crisis could hurt *everyone* in the dairy category.

Together, they encouraged the Innovation Center to make food safety one of its unifying priorities.

"Larry was concerned that perhaps not as much attention or education was happening across the industry," Wilkin says. "He began to talk with some of the CEOs who were part of the Innovation Center's efforts, and they came away with the sense that we need to do something more intentioned in terms of training, education, best practices, and more outreach."

Soon, that vision became a reality, and about a dozen leaders from different businesses left their competitive mindsets outside the doors of a Wisconsin hotel meeting room and huddled for the first time as a single industry. Wilkin remembers Tom Hedge, a former executive with Schreiber Foods, leading that first committee meeting and asking the room, "So, what kinds of problems are you seeing?"

His question was met with somewhat of a memorable thud.

"When you begin to talk about 'here's what I do sanitation-wise,' those get very close to the vest and typically that's not the type of information that is shared, even among friends," she says. "It was awkward and difficult. However, the people we brought together were all in the quality food safety arena. Gradually, there was an opening up, which really helped."

A Spirit of Collaboration

The Innovation Center is proving that a large, complex industry is stronger when it works with a collective spirit on important issues such as food safety. Led by CEOs and chairs of dairy cooperatives, processors, retailers, and associations, the Innovation Center provides a precompetitive forum for the dairy community to develop credible, industry-aligned tools and resources to advance U.S. Dairy's long-standing commitment to social responsibility and continuous improvement (see "Innovation Center for U.S. Dairy Food Safety Resources," below left).

More than 60 percent of U.S. milk production is represented by Innovation Center board members, including many of dairy's biggest companies, such as Hilmar, Schreiber, Leprino, HP Hood, Land O'Lakes, Foremost Farms, Agri-Mark, Dean Foods, and Dairy Farmers of America.

Keeping cheese, fluid milk, dry ingredients, yogurt, and ice cream safe from pathogens has their full commitment. As a result, Wilkin says, the buy-in of that original food safety vision of "working as one" is today fully embraced.

"Some of the newer people who participate in the Innovation Center are somewhat shocked at how frank our conversations are," she says. "We have a (dairy company) president who came from the soft drink industry and he said, 'We didn't talk to each other. I'm surprised at what dairy does through the Innovation Center.'

"It always amazes him. It amazes a lot of people."

Innovation Center for U.S. Dairy Food Safety Resources

To strengthen manufacturing practices in all dairy processing facilities, advance science-based tools, and diminish food safety risks that could compromise the reputation of the U.S. dairy industry, the Innovation Center for U.S. Dairy provides workshops, tools, and guidance documents.
All materials are available at www.usdairy.com/foodsafety.

- Dairy Plant Food Safety Workshops – Design checklists, scientific reference materials, registration
- Dairy Supplier Food Safety Management Workshops – Risk assessment calculator, best practices guide, workshop registration
- *Listeria* Guidance for the U.S. Dairy Industry – Comprehensive guidance for manufacturers of all sizes, free online in English and Spanish: www.usdairy.com/foodsafety
- Spanish-Language Tools – *Listeria* guidance document, checklists, and Sanitation Standard Operating Procedures, examples available in Spanish
- *Listeria* Research Consortium
- Traceability Guidance

The committee follows several action platforms, including:

- Pathogen controls (Dairy Plant Food Safety and Supplier Food Safety Management workshops)
- Artisan/farmstead cheese food safety
- Pathogen control guidance documents (comprehensive *Listeria* guide issued; broader pathogen guide under development)
- *Listeria* research consortium
- Traceability

These committee members–Stubbs's "all-stars"–are some of the dairy industry's leading experts who focus on food safety for their respective organizations.

"These are people at the top of their field and they work for private companies," Stubbs says. "The companies are fully committed to this effort and have given the committee access, for example, to the best pathogen experts in the world. Companies happily share the best sanitation experts, microbiologists, people with 30 years' experience in equipment design, and other 'internal' experts for the greater good."

The committee meets in-person twice a year and convenes for monthly calls. Stubbs says they share best practices, discuss workshops, and *Listeria* research. At the end of the call, they save time for open dialogue. This openness builds trust, and the sharing of best practices and insights, plus having access to an arsenal of experts with skill sets for any need, is what keeps the momentum going strong.

"As a company, we get to contribute, and when you give, you get to receive," Travis says. "I used to be surprised by the collaboration, but you soon realize that we all live through a lot of the same things, and it's easier to move faster when you understand them together. The research work we're doing as a consortium would be a lot more expensive and complicated for us to do as individual companies.

"So, it's really easy to align the Innovation Center work with my day job. I have a lot of regular interaction with the committee members and it keeps Hilmar from having to reinvent the wheel."

Listeria in the Crosshairs

One area the committee identified as needing an industrywide focus was *Listeria monocytogenes*. So, in 2015, the group created the *Listeria* Research Consortium that was built with funding from core dairy companies that chose to contribute and from another farmer-founded organization, National Dairy Council. To date, the consortium has raised more than $1 million and funded nine projects aimed at:

- *Listeria* controls in products and in the plant environment
- *Listeria* virulence research
- Surface-ripened and fresh cheeses

The *Listeria* control guidance document was another activity of the team. The guide, published in 2015 and revised in 2017, offers a comprehensive approach to controlling *Listeria* in the dairy industry. It was authored by 13 industry experts and reviewed by academic and government experts. Last year, the materials were translated into Spanish. It is available for free download at www.usdairy.com/foodsafety.

The Innovation Center's ability to leverage processors' expertise and best practices allows it to share broadly through several training workshops. Two trainings that deliver an effective impact are the Dairy Plant Food Safety Workshop and the Supplier Food Safety Management Workshop.

The Dairy Plant Food Safety Workshops are 2-day, hands-on sessions designed to cover best practices and uniform approaches to in-plant pathogen control programs. Thirty-eight sessions have taken place since 2011, and more than 2,000 professionals have attended.

The Supplier Food Safety Management Workshops focus on how to build a supplier quality program and mitigate risk from materials and services. These also are 2-day interactive workshops that reach an audience of quality, supplier quality, and purchasing professionals. Thirteen sessions since 2011 have provided risk identification and mitigation tools to more than 200 people.

While it's dairy's largest companies driving commitments such as these, Stubbs says committee members have a collective ability to look well beyond themselves. In fact, smaller artisan/farmstead cheesemakers also benefit from the Innovation Center's heavyweights. The mindset is that companies of all sizes suffer when consumer confidence is lost, no matter who has an issue.

While artisanal and farmstead cheesemakers account for only a small percentage of U.S. production volume, the number of companies is increasing, multiplying the potential for risk.

Resources for Artisanal and Farmstead Cheesemakers

To support the rapidly growing artisan dairy community, the Artisan Food Safety Advisory Team was formed to enhance food safety and pathogen control with clear, easily accessible resources and training.

- Food Safety Basics for Artisan Cheesemakers – Online food safety course through North Carolina State University, accessible anytime from anywhere: www.usdairy.com/artisan
- Safe Cheesemaking Hub – Centralized food safety links for cheesemakers powered by the American Cheese Society: www.safecheesemaking.org
- Hands-on Food Safety Coaching – Work sessions to help artisan and farmstead producers develop/improve their food safety plan: dairyextension.foodscience.cornell.edu/programs/artisan-dairy-food-safety-coaching
- Ice Cream – Food safety hub and online class coming soon
- Support Hotline – E-mail support for artisan and farmstead producers: dairyfoodsafetycoach@cornell.edu

Stubbs said there are about 1,000 cheesemakers devoted to meeting this growing consumer demand, and it's why the Innovation Center formed the Artisan Food Safety Advisory Team (see "Resources for Artisanal and Farmstead Cheesemakers," p. 44).

The Innovation Center conducted 21 training sessions from 2012 to 2016, reaching 750 artisan/farmstead cheesemakers and regulators. To make the materials more accessible, the Innovation Center partnered with North Carolina State University (NCSU), the American Cheese Society (ACS), and others to build an interactive online version of the course.

The course–"Food Safety for Artisan/Farmstead Cheesemakers"–includes five interactive segments focused on the importance of food safety, food safety hazards, preventive controls, regulatory considerations, and product/environmental monitoring. Additional training guides and resources are available at www.safecheesemaking.org, which is hosted by the ACS, and there is also in-person outreach to help companies write their own food safety plan. The commitment to the artisan community extends to research efforts as well.

"There was uniform agreement that the number one focus needed to be artisan dairy," Stubbs says. "This is where the vulnerabilities are, but those [artisan] companies don't have the same resources. There would not be much research funding for queso fresco or Brie because companies who make them are not big enough to pay for it. So, we steered much of our research funding to Hispanic-style and surface-ripened cheeses for two reasons: One, we have seen outbreaks historically in this category. Two, if you can help these products, it helps most of the rest because high-moisture, neutral pH cheeses are the hardest nuts to crack."

Travis says it's a commitment that is well worth the investment from Innovation Center members.

"We all have learned that when smaller players stub their toe and have an issue, the whole industry is affected," he says. "We don't just focus on a truly competitive mindset, where as long as we don't have a problem, there isn't a problem. If anyone has a problem, the whole industry has a problem."

Academic Support

The Innovation Center has surrounded itself with experts beyond those from dairy companies. It has built many relationships across the world of academia, including those through the National Dairy Foods Research Centers. This program encompasses the resources and skills of a network of universities divided into six

regional groups across the U.S.

Since 1987, the dairy centers have received financial support from dairy farmers and processors to collaborate with organizations such as the Innovation Center. Each center has its own proficiencies, such as the Northeast Dairy Foods Research Center at Cornell University, which is a go-to source for food safety.

Dr. Sam Alcaine, a professor at Cornell's Department of Food Science, is part of the Innovation Center's artisan efforts and conducts research. He works with the Innovation Center and companies to help them understand the latest research and findings, which are always evolving.

"The challenge in the processing and ingredients environment is what we didn't know before," he says. "Twenty years ago, we didn't quite know about *Listeria* and now we know about it and that requires different practices to be put into place."

Alcaine has led workshops for dairy companies and their employees across the org chart, "from the executives on down to the linemen," he says.

Much of his outreach centers on helping smaller companies understand and follow the Food Safety Modernization Act (FSMA) that was signed into law in 2011. FSMA provides the U.S. Food and Drug Administration the authority to regulate how foods are grown, harvested, and processed.

In October 2017, Alcaine, with the Innovation Center, NCSU, and the University of Connecticut, secured a 3-year, $400,000 U.S. Department of Agriculture grant through the National Institute of Food and Agriculture. This provided the resources to conduct FSMA-focused food safety plan writing and coaching sessions nationwide. The target of this effort is artisanal cheese, ice cream, and other small dairy manufacturers. Alcaine, with regional extension help, examines their food safety plan and provides coaching where vulnerabilities exist.

"Even before this grant, we realized there were gaps," Alcaine says. "We then wrote this grant with the idea of bringing in food safety experts from academia and large companies, so we could sit with the artisans and help them understand a food safety plan and see the risks and understand what they need to put in place. A lot of times, these are one- or two-person operations and they're wearing a lot of hats and it's easy to drop the ball."

In addition to the Innovation Center-coordinated classes, Alcaine's outreach stretches to medium-size companies, where he performs audits to help them identify weaknesses.

"It's really important when you understand there are problems that could impact everybody," he says. "If we all have a 'we're in this together' mentality, that drives funding for the science to figure out where the problems are and then develop solutions. And it's not just for the dairy industry. A lot of the learnings we discover are applicable to other foods."

Unforeseen Benefits

When Stubbs reflects on the committee's highlights over the last several years, the *Listeria* work bubbles to the top of tangible results for him. Yet, he offers a bigger-picture perspective. It's the idea that people from competing companies have found common ground and camaraderie through the Innovation Center.

He never takes the uniqueness of it for granted.

"It's pretty neat that 30 companies have been very active in food safety work, and they give us their top subject matter experts," he says. "They let us have them 8, 9, sometimes 12 days a year, and when I talk to those individuals, they love doing it.

"We're providing an outlet for sharing and collaboration that people are eager to do. It's an opportunity that is safe and their companies support. It's amazing how many volunteers we have and how deep they go and how much they work. It's the power of getting all those great minds together."

Travis has experienced an unexpected benefit from being involved with the group. He sees people from his company who have blossomed professionally by having a platform through the Innovation Center.

"Once you get them out of their plants, out of their offices, and get them in front of their peers doing a presentation or trying to convince someone that a different approach is better, you begin to impact professional development," he says. "And that's something that you hadn't even thought about.

"I have seen a lot of people really put on a lot of polish as they have gone through the Innovation Center programs. That's a nice benefit that we sometimes don't talk about."

Wilkin's extensive knowledge base and strong voice have created a mentoring presence among her Innovation Center peers.

"I have Edith on speed dial," Travis says, probably only half-kiddingly.

Wilkin, too, has a list of food safety accomplishments that she is proud of. There's the *Listeria* research consortium…the various workshops...the thrill of discovering new knowledge together…helping the artisans…the best practices and guidance documents… the engagement with regulatory officials and academia…and so on.

"Are all of these things a surprise to me?" she asks. "I guess in thinking about being in a hotel meeting room in Green Bay, Wisconsin, way back when, none of us thought we'd get to this point and in pretty short order. We did our first pilot workshop in 2011, and a mere 7 years later, look where we are today with all these moving parts.

"When you think about the resources companies put into doing this sort of thing at a time when people are short on help, have too much work going on, and are dealing with competitive pressures–we've stayed committed to doing all of this together. That gives you a very warm feeling about the dairy industry as a whole." ■

Scott Wallin *is vice president of industry media relations and issues management at Dairy Management Inc.*

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By Joanna Gilbert

Fonterra's Food Safety Transformation

Using a precautionary recall to drive changes in food safety culture

Fonterra is a global dairy nutrition company sharing the nutritional benefits of dairy with over a billion people every day. It's a cooperative made up of around 10,000 farmers and 22,000 people, working alongside partners, suppliers, customers, and consumers, and headquartered in Auckland, New Zealand. It's the largest exporter of dairy in the world, with product going to over 100 countries. As well as fresh milk, the company produces ingredients for the consumer and foodservice industries, plus ingredients used in everything from advanced medical nutrition to everyday dairy products to infant nutrition to milk powders.

The dairy industry has been part of New Zealand since the 1800s, with the first dairy cooperative established in the South Island in 1871. Fonterra was formed in 2001 when two of New Zealand's largest dairy cooperatives merged with the New Zealand Dairy Board to create Fonterra. The Cooperative has an annual turnover of around NZ$17 billion, with a core ingredients business exporting under the NZMP brand, as well as fast-moving consumer goods businesses globally. Currently, it has 51 operations sites in 11 countries across five continents and sources milk from Australia, China, Latin America, New Zealand, and Sri Lanka.

Putting a Strong Focus on Food Safety

The importance of creating a strong and sustainable culture around food safety and quality (FSQ) was highlighted in August 2013 during a precautionary recall of a whey protein concentrate product (WPC-80). WPC is used in a variety of ways, including in yogurt, beverages, and dairy desserts. It is also used in infant formula and sports nutritional supplements. During extensive product testing, Fonterra had concluded there was a minute potential food safety risk with three batches of WPC-80. Further testing showed there was no risk to consumers, but in the interim, Fonterra contacted its commercial customers and publicly announced a precautionary recall.

This precautionary recall prompted Fonterra to look more closely at its practices and beliefs around food safety, resulting in a recognition that the food safety culture could be stronger, and the predominant focus was on milk processing and operational efficiency. As a result of this reflection, a 5- to 10-year FSQ strategy was developed, with the objective of fundamentally changing the mindset and behavior of the business.

Figure 1. The Trust in Source Strategy

This strategy is called "Trust in Source," and through it, Fonterra is constantly focusing on reducing risk, building trust in its people, customers, and consumers, and in the food it produces, as well as creating value for the business.

To do this well, the Cooperative started with its customers and consumers, taking on broader insights from global communities to understand what matters most to them. As a result, the Trust in Source strategy starts with consumers and what they need to ensure they can trust the food Fonterra is making, that it meets their expectations, and then works right through Fonterra's entire supply chain back to the farmers, vendors, suppliers, and other key stakeholders (Figure 1).

Changing the Food Safety Culture

The 2013 event sparked a number of immediate actions. Fonterra showed early commitment by recruiting dedicated, specialized personnel to lead the food safety culture transformation and ensuring they had access to globally recognized thought leaders in this field, such as Frank Yiannas, then the vice president of food and safety and health at Walmart. Alongside learnings from Fonterra's existing strong health and safety culture, the Yiannas model was adopted as a cornerstone of the Trust in Source transformation program (Figure 2).

Team members were recruited as specialists in change management, human behaviors, marketing, and adult learning and communications. Having a dedicated team was a deliberate decision made by the CEO and Fonterra management team to ensure a single-minded focus to make and sustain the change to having the desired food safety culture.

The team developed measurement systems in partnership with Frank Yiannas to measure the maturity of the food safety culture within the organization. From this point, plans were cocreated with business unit leadership teams that reflected the teams' individual cultures. This enabled the teams to leverage the creative tools, science, and capabilities to deliver a balance of company-wide and specific initiatives and engagements to make the transformation to a sustainable food safety culture. Today, the Fonterra management team and board receive regular reports from the FSQ team regarding delivery on its strategy and the maturity of Fonterra's FSQ culture, with significant progress being demonstrated over the past few years.

Showing Evidence of Positive Changes

Not only have Fonterra's internal metrics shown improvement, but feedback from its customers demonstrates that these changes are also making an impact. For example, last year, independent research benchmarking showed that Fonterra's customers in total believed that every product group produced was performing at or above a world-class standard, with feedback such as:

"Fonterra products stand out in terms of the quality (product performance) when many products are compared together. A high level of customer loyalty can be seen because of such excellence in quality."

"Works very closely with customers to understand issues, needs, and processes to improve service level of performance and build long-term relationships."

Key to the speed at which the culture shift happened was strong, focused leadership partnered with a dedicated team that leveraged a broad range of approaches to maximize the impact, uptake, and integration of the desired future behaviors. The aim was to build a strong and thriving culture throughout the workforce and beyond, integrated into the "business as

Figure 2. The Yiannas Food Safety Culture Model

usual" workings of the organization to ensure sustainability.

Consistent communication then concentrated on two key areas:

1. Making FSQ a personal focus on what it means to "me" and not an amorphous "business priority." This is best exemplified by the "safety is a promise" campaign that Fonterra continues to build on while also integrating into regular business activities such as on-boarding, training, and communications. This campaign encourages every employee—from the senior management team down—to make their own personal safety-related commitments and promises. It is enhanced through stories such as that of John, a forklift driver at the Kauri factory in Whangarei, and supported through additional branding and collateral such as the promise walls at all factory entrances, red-line promise statements in staff changing rooms, and regular stories shared across the organization, all bringing the concept of personal responsibility into the everyday work environment of the workforce.

2. Growing the understanding of what being a food company means. Fonterra has significantly changed the understanding about what it does. Rather than processing a "wall of milk" to different specifications, Fonterra recognizes that its products are either ingredients in food or food items themselves and are eaten by people all over the world. Simple engagements—sharing food, telling stories from customers and consumers, producing maps for each factory of where their food goes—all contributed to this shift. In addition, Fonterra had the opportunity to create a step-change engagement from the start of the 2015 season (July 2015) using a "supply chain experience" that now includes virtual reality, filming, and gamification to provide a variety of ways to communicate to and engage various audiences. Fonterra's employees can now speak with consumers who eat the food they make and hear why they chose to buy food made by Fonterra and the impact that has in their lives.

"Not only have Fonterra's internal metrics shown improvement, but feedback from its customers demonstrates that these changes are also making an impact."

Sustaining the Changes in Food Safety Culture

Three things have made the most difference in creating our sustainable food safety culture:

1. Driving Leadership and Commitment

This was driven initially by the precautionary recall but has been sustained since 2013 through a deliberate approach of ensuring regular and ongoing reporting, cadence around engagement, and support as asked for from the Fonterra management team to lead the way while modeling the behaviors it is seeking. This is supported with strong governance for FSQ, including a range of technical stakeholders and business leaders. It included spending time with the management team and senior leaders to clarify Fonterra's FSQ expectations and then leveraging these as the "true north" or "guiding light" for all forthcoming FSQ decisions and behaviors. In addition, it tapped their keenness to engage on this topic on a global basis by participating as a member of the Consumer Goods Forum's Global Food Safety Initiative Technical Working Group on Food Safety Culture, workshops, and presentations at conferences and industry-wide events, working alongside Fonterra's vendors and partners on their own food safety culture strategies as they see the benefits in learning from others and sharing their stories.

2. Understanding Its People

The transformation team understood that to change behavior, it had to engage people in a way that would reach them and not maintain one style of communication or approach. The challenge was to identify the audiences, what mattered to them, and how the team could reach them. The team was also faced with an audience that had been through a lot of change. It needed to find a way to resonate with them all, quickly and on a global scale.

The program was nicknamed "Finding Steve"—and in finding Steve, the business gained an excellent understanding of the attributes, behaviors, and states of mind of key audiences in building the food safety culture the team was looking for (Figure 3).

"Finding Steve" leveraged the customer segmentation concept used in marketing. It was based on gathering data, holding focus groups, talking to key stakeholders such as unions, and getting an overall picture of the workforce the team needed to engage with. The process began in 2014 with the New Zealand manufacturing worker (the original "Steve") and will continue as a key enabler to sustain the change. Through this process, the team discovered a number of distinct people profiles across Fonterra's global business. These profiles formed the basis of the decisions made as to the methods of communication with various business units, sites, and operating entities. This allowed the transformation team to cocreate and test initiatives with particular "Steve" groups, so that when they deploy something, they know it will resonate with the target audience, minimizing ineffective communication and avoiding food safety communication becoming "white noise."

3. Leveraging Science, Creativity, and Innovation

Through leveraging the science of human behavior and taking a creative

Figure 3. "Finding Steve" Program

and innovative approach to problem solving, Fonterra delivered initiatives that were compelling and connected to its people. One example of this was through engaging an adult learning specialist with one of Fonterra's key business partners, Sysdoc. By working alongside their learning team, the approach to annual food safety compliance training was revolutionized. Together, a very procedural slide presentation with low learning outcomes was turned into an engaging board game, which was visually customized to build rapport with its audience. This board game method has proven to deliver strong learning outcomes but also to be far more than just an educational tool; it directly impacts the culture and behavior around food safety as a result of the design and the people who facilitate it. Consequently, the relationship between food safety roles and the operators within the business has become far more transparent. The game not only encourages but also legitimizes the discussion of tough topics–topics that might otherwise be avoided in the presence of the FSQ specialists. From a behavior and culture perspective, this relationship dynamic change is hugely powerful, and operations staff now approach the group food safety team, without prompting, much more frequently.

Moving Forward as a Better Company with a Stronger Food Safety Culture

Fonterra's new level of commitment to FSQ has led to a change in behavior so significant that its customers and partners use language to describe it–"old Fonterra" versus "new Fonterra." Feedback from customers and quotes that are shared within the business are largely consistent and positive as to the change in attitude, results, and focus that people have perceived toward FSQ. This is entirely down to the underlying cultural and behavioral changes that continue to drive the business changes people are noticing.

The strength of this food safety culture is evident not only expressly in artifacts, policies, and procedures, but also intrinsically in the values and beliefs of people at all levels of the organization. Independent research has recently demonstrated that Fonterra employees now better understand their individual responsibilities as part of a food company and are better empowered, encouraged, and enabled to "stop the line" or make the right call for the safety of Fonterra's people and the products they are making.

But most importantly, why Fonterra does this is outlined in Figure 4. ■

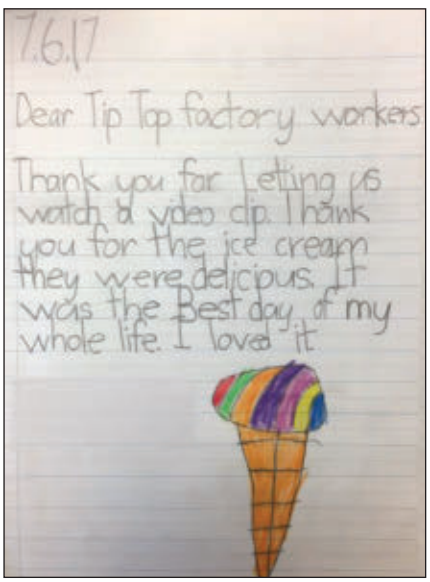

Figure 4. Child's "Testimonial"

***Joanna Gilbert** is the Director, Reputation Shift, Corporate Affairs, for Fonterra Cooperative Group Limited in Auckland, New Zealand.*

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

Snacking: A Booming Trend in the American Lifestyle

Everybody needs to eat to have energy to sustain life. As a result, food is a necessity, but some people enjoy eating so much that they consider it a hobby or a pastime. The 21st century has seen great population growth and extremely busy lifestyles, making the availability of food all the more critical. Busy lives and not enough time to cook from scratch have made it so that most people no longer go home and cook a meal for themselves and their families.[1] Without the ability to put in the time to cook, Americans are resorting to convenience foods. The most common form of convenience eating is snacking. Over the years, snacking has taken on many different definitions, but snacks were originally intended to be smaller portions of food eaten to fight off hunger between meals. The concept of three square meals daily is becoming obsolete because nowadays people snack for reasons besides feeling hungry, such as getting rid of cravings, staving off boredom, improving metabolic rates, alleviating stress, boosting nutrient intake, controlling weight, and simply because they believe that eating often is good for one's health.[2] Other reasons people may choose to snack are celebrations and special occasions.[3] It has also now been estimated that 94 percent of people living in the United States consume one or more snacks every day.[4] Because snacking has become so popular in recent years, this article will focus on popular trends in the food industry as well as quality and safety issues that may result from these new trends.

Although they're a safe food overall, it is still critical to implement necessary food safety procedures for snack foods

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Snacking Trends

Responsible Snacking

Recent trends in snacking demonstrate how this concept has really evolved in recent years. First, as described by *Forbes*,[4] most consumers, especially the millennials, often feel responsible for what they do for themselves as well as their community and the planet. When deciding to purchase snacks, people typically ask themselves if what they buy will better themselves or the communities they represent. As a result, consumers are choosing to snack on foods that are clean, organic, less processed, contain fewer ingredients, lack genetically modified organisms, additives, or antibiotics, and are locally grown even if the snack costs more money. There have also been snacking trends associated with certain times of the day such as consuming healthy, energizing, and light snacks in the morning and eating sweet and savory snacks in the evening.[4]

Flavors with Global Influence

People these days are also more open to the experience of unusual flavors and are more willing to eat foods that are bold, spicy, and culturally diverse.[4] One category of snacks that has seen a huge change in flavor preferences is meat products, because people are now choosing flavors like Korean barbecue, sweet barbecue, bourbon barbecue, black cherry barbecue, and seasoned barbecue as opposed to cayenne, basil citrus, tangy barbecue, and red pepper.[3] With new flavors comes world influence, and some areas of the world that have influenced flavor in recent years include Asia, Central America, and even the United States and Canada.[3] Three popular Asian flavors that have grown significantly in popularity are cardamom and tikka masala from India and matcha powder from Japan. Other Asian flavors rising in popularity are garam masala, pistachio, rose water, saffron, and tamarind. Some popular Central American flavors are avocado, guava, green olive, key lime, mango, paprika, dark rum, sour orange, and sofrito, while one popular Central American snack is plantain chips. Popular flavors from the United States and Canada are watermelon, rhubarb, Cape gooseberry, maple, huckleberry, molasses, and brown butter. New flavors have resulted in greater variety and availability as there has been a growth in the number of places for consumers to meet their treat needs with the addition of specialty candy stores across America, the vending evolution, and the impact brought on by quick service and fast casual restaurants. These trends are all new and exciting but will not maintain popularity if they are of low quality or people are getting sick.

Quality vs. Safety

Although snacks are one of the safest foods in the market, it is still critical to implement the necessary procedures to attain the highest level of food safety and quality.[5] Even though quality and safety go hand in hand, it is important to remember that not all food of poor quality is unsafe, but all unsafe food is of poor quality. An example from the snack industry is the oxidation and staling of potato chips, which cause the food to taste terrible but will not allow pathogens to grow due to low water activity, making it an issue of quality only. An example of a safety issue would be spices that were irradiated improperly, whether it be too much irradiation or irradiation from an unapproved source resulting in a radiological hazard. Too little or no irradiation can lead to microbiological hazards such as *Salmonella*, *Clostridium botulinum*, and *Escherichia coli* O157:H7.[6]

Allergens

A lot of popular snack foods are made from peanuts, tree nuts, wheat, soy, milk, and eggs, which are six out of the eight most common allergens that must be labeled if present in any foods sold in the United States. This labeling also applies if a food is processed in a manufacturing facility that processes any of these allergens. Since allergens can be introduced into foods by accident and some people who suffer from food allergies may not have the time to read the label's fine print, it is crucial to have an allergen management program in many areas of food processing (see "The Hazards of Food Allergy," below[7]). These areas of food processing include vendor approval, product development, proper labeling, receiving, warehousing and storage, production control, sched-

The Hazards of Food Allergy[7]

Food allergies are very common and can affect just about anybody. In March 2018, a 12-year-old girl living in Georgia had a fatal allergic reaction to a granola bar that may have contained peanuts. Before this incident occurred, she had tested positive for a peanut allergy when she was 3 years old and had had several less severe reactions since the diagnosis. In March, she was enjoying a granola bar (a brand that she had eaten before), but she started to experience anaphylaxis while riding the school bus. She did not have an EpiPen available because she did not feel as if she needed one from previous less severe reactions. As her symptoms began to worsen, the bus driver brought her to the nurse's office of another school, where she was treated with EpiPen injections until an ambulance arrived. The ambulance took the girl to a hospital, but the reaction was so severe that she had to be flown to another hospital. Doctors did everything they could, but sadly, the happy and energetic girl who enjoyed biking and ice skating, and could light up a room wherever she went passed away 2 days later. How she got exposed to the peanuts in the first place is still a mystery, but it is assumed that it probably had something to do with the peanut allergen not being recognized on the label of the granola bar she was eating on the school bus. The lesson learned from this story is to be consistent and thorough with labeling allergens, and if any error occurs, the food should be recalled.

uling, cleaning and sanitizing, control of rework, product identification and recalls, and education of management and staff.[5]

Mycotoxins and Acrylamide

Allergens are not the only chemical hazard to be aware of, as snacks that are grain- or seed-based could contain mycotoxins, the worst of which is aflatoxin, which causes liver disease. Companies that use baking, frying, or oven cooking to produce snacks must be aware of acrylamide because the ingestion of too much of this compound can be carcinogenic.[5] Acrylamide has hit the snack food industry very hard over the past decade, necessitating the use of alternative processing.

Post-Lethal Handling

Although most snack foods can be viewed as perfectly safe, it is important to avoid mishandling, abuse after processing, incorporation of contaminated ingredients, and failure to manage certain processing steps prior to consumption.[5] One pathogen that has been common in snack foods is *Listeria monocytogenes*.[8] Some of these foods are ice cream and hummus due to their high water activity and storage at refrigeration temperatures. *L. monocytogenes* post-lethal processing contamination has caused multi-year recalls and outbreaks within the ice cream and hummus categories. Companies have invested millions of dollars in mitigation, control, and prevention strategies. This includes but is not limited to new construction, new equipment, enhanced sanitation programs, and hiring additional experienced food safety/quality assurance team members. One company even stopped production and outsourced to comanufacturers of their product because the pathogen was found to be resident within the processing plant and unable to be effectively mitigated after multiple deep-clean sanitation and disinfectant applications.

In the last few decades, there have been several recalls related to *Salmonella* in everyone's go-to snack, peanut butter, which demonstrates that some conditions, like low water activity, make it nearly impossible to remove a pathogen once the product is exposed.[5] Other nut butters have also been involved in serious pathogenic outbreaks and recalls.

Another snack item that may seem extremely safe is beef jerky; however, some pathogens can survive the harsh drying process used to make this food, and killing off these pathogens would require additives such as nitrites which are known to form carcinogenic compounds.[9] Beef jerky is a new artisanal movement enabling small processors to open for business. Many artisanal jerky makers are marketing their product *(continued on page 63)*

Salmonella-Tainted Cereal

When one hears the word *cereal*, he or she will often think of a breakfast food, but cereal is also very popular as a snack food item, especially for toddlers. Unfortunately, if you pack cereal as the "easy" snack for your little one(s), you may want to be careful which cereal you choose. One popular cereal in particular, Kellogg's Honey Smacks, was the recent subject of a recall associated with the bacterial pathogen *Salmonella*, which was reported in 33 states.[10] For those unfamiliar with this product, it is a puffed-wheat, sugarcoated cereal. In addition, most people are somewhat familiar with *Salmonella*, but some people do not know that this bacterial genus is responsible for the majority of foodborne illnesses linked to bacteria, is often present in improperly cooked eggs and poultry, and is known to have more than 1,000 strains. Despite the Honey Smacks recall issued on June 14, 2018, making the sale of this product illegal in the United States, it was reported about a month later that cereal containing traces of *Salmonella* was still available for sale at certain grocery stores.

Food Safety News[11] reported that, "Investigators have laboratory confirmation that the outbreak strain of *Salmonella* Mbandaka is in the manufacturing facility and in unopened packages of the cereal. As of June 12, the food manufacturer—which Kellogg's hired to make the Honey Smacks—stopped producing the product." While no individuals died, 34 out of the 135 people who became sick were hospitalized as a result of the outbreak.[10] Although *Salmonella* is not usually deadly, it can make its way through the intestines to the bloodstream and to the rest of the body.[12] As a result, *Salmonella* victims can suffer serious side effects such as diarrhea, fever, and abdominal cramps, and these effects can last from 4 to 7 days on average.[10] The U.S. Centers for Disease Control and Prevention (CDC) issued a statement that warned people not to eat Kellogg's Honey Smacks no matter what package size or sell-by date and also encouraged people who have recently consumed the cereal with no side effects to discard their cereal or return it for a refund.[13] In addition, it was recommended that if a bag of cereal is missing its original box and the owners have forgotten the name and type of cereal, the consumers should dispose of the cereal; for those who keep their cereal in containers other than cereal boxes and bags, they also should discard the cereal and clean and sanitize the container with water and dish soap.[14] CDC requested that anybody who sees Kellogg's Honey Smacks cereal being sold notify his or her local U.S. Food and Drug Administration (FDA) consumer complaint coordinator.[12] CDC and FDA investigated the source of the contamination with the help of state and local health officials throughout the U.S., and identified specific problems at the manufacturing plant.

In conclusion, it is important that people avoid eating Kellogg's Honey Smacks marked with a "best if used by" date before June 14, 2019, as well as any similar cereals and always be aware of the news, because no one knows when their favorite snack food may be the subject of a recall.

By Peter J. Taormina, Ph.D.

Revised USDA Cooking and Cooling Compliance Guidelines: Impact on Validation and Process Deviation

Agency clarifies when more pathogen testing is expected

There is nothing more essential to meat and poultry safety than proper cooking to destroy vegetative bacterial pathogens of concern and cooling promptly to prevent outgrowth of spore-forming bacterial pathogens. Since 1999, U.S. federally inspected meat plants have been required to cook beef, roast beef, and cooked corned beef products to achieve at least a 6.5-log reduction of *Salmonella*, or to process to an alternative lethality (e.g., at least a 5-log reduction), per 9 C.F.R. 318.17(a)(1). The U.S. Department of Agriculture Food Safety and Inspection Service (USDA-FSIS) requires that cooked uncured meat patties must be processed to meet or exceed the times and temperatures listed in 9 C.F.R. 318.23, which will achieve a 5-log lethality. Cooked poultry products must be processed to achieve at least a 7-log reduction of *Salmonella* per 9 C.F.R. 381.150(a)(1). For other ready-to-eat (RTE) meat products, establishments must ensure that products are safe for consumption (i.e., free of pathogens) to produce unadulterated product and meet Hazard Analysis and Critical Control Points (HACCP) requirements. Also, establishments are required to cool RTE products to achieve "stabilization" per 9 C.F.R. 318.17(a)(2). "Stabilization" means there can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum* and no more than 1-$\log_{10}$ multiplication of *Clostridium perfringens* within the product as it passes through the growth temperature range of pathogens during cooling down to refrigeration temperatures.

Updated Compliance Guidelines

To aid the industry in meeting cooking requirements, FSIS had published a document called *Appendix A, Compliance*

Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products in 1999. After revisions in 1999, 2011, and 2012, FSIS issued the most substantial revision to these guidelines in June 2017, to provide clarification of regulatory requirements for RTE products [Salmonella *Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A*]. The revised compliance guideline also provides additional options for achieving lethality of *Salmonella* in RTE products, updates the lessons learned from food safety assessments, and combines and replaces information from previously issued guidance documents. In June 2017, FSIS also published *FSIS Appendix B Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)* of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products" (64 F.R. 732) and FSIS Directive 7110.3, Rev. 1, *Time/Temperature Guidelines for Cooling Heated Products,* dated January 24, 1989, and the June 2017 *FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B June 2017 Compliance Guideline*.

Although both revised compliance guidelines were emphasized to not be considered requirements but rather a best practice, guidance, or recommendation, the recent updates created concern across the industry due to new clarified stipulations concerning the use of safe harbors for cooking and cooling in appendices *A* and *B*, respectively. FSIS published Notice 17-18, which stated that industry had until March 22, 2019, to review "new" revised appendices *A* and *B* to determine whether additional scientific support was needed to support the establishment's process per 9 C.F.R. Section 417.5(a)(1) and to validate any changes to be made to the establishment's process to follow the new guidelines or additional support over 90 calendar days [9 C.F.R. Section 417.4(a)(1)].

Revised Appendix A

Most cooked meat and poultry processors cite the *Appendix A* safe harbor time and temperature combinations as the scientific basis for their critical limits for cooking to eliminate *Salmonella*. Indeed, the use of *Appendix A* extends beyond meat and poultry cooking, as producers of other products such as veggie patties, meatless frankfurters, or meatless entrees sometimes also rely on these guidelines. However, since the *Appendix A* cooking times and temperatures were based upon thermal

Year	Random Total Tested	Positive Samples No.	Positive Samples %	Risk-Based Total Tested	Positive Samples No.	Positive Samples %
2009	2,761	1	0.04	8,158	3	0.04
2010	3,152	1	0.03	8,707	3	0.03
2011	3,293	3	0.09	8,865	8	0.09
2012	3,353	1	0.03	7,650	5	0.07
2013	3,263	4	0.12	8,898	3	0.03
2014	3,356	2	0.06	9,750	3	0.03
Total	19,178	12	0.06	52,028	25	0.05

Table 1. Salmonella *spp. in RTE Product Samples, 2009–2014*

death curves for *Salmonella* in beef emulsions in tubes,[1] utilization of these parameters is not necessarily valid for every product matrix.

The impetus for the revision to *Appendix A* is in large part the agency's desire to provide clarification about humidity in cooking. FSIS also referred to information from food safety assessments in several establishments that noted lack of control of *Salmonella*, as well as several *Salmonella* outbreaks related to RTE meat and poultry products, which appeared to be not related to inadequate cooking but rather to Good Manufacturing Practices or post-lethality recontamination of products. The agency's baseline data of *Salmonella* in RTE products dating back to 2009 revealed an overall rate of 0.05 to 0.06 percent (Table 1). Pork products were the sources of over half (21/37) of all *Salmonella*-positive RTE samples.

The revised document includes a definition of pasteurization and guidance on how to label products as pasteurized. It also provides lethality requirements for certain RTE products, an overview of hazards of ingredients added post-lethality, and guidance on post-processing handling and sanitation. The guidance clarifies use of humidity in lethality processes, the time-temperature tables from *Appendix A*, and tables for achieving lethality in chicken and turkey RTE products and in nonintact meat chops, roasts, and steaks. The tables for chicken and turkey include time and temperature safe harbors based upon fat content. There are recommendations on how to support a 5-log reduction of *Salmonella* and clarification on how establishments can support an alternative lethality of at least 5-log reduction of *Salmonella* for roast, cooked, and corned beef as required in 9 C.F.R. Section 318.17(a)(1). FSIS

If you selected a time/temperature greater than or equal to 145 °F plus applicable hold time (e.g., 4 minutes from Appendix A*) with a cooking time of longer than 1 hour,* **select from the following options to maintain relative humidity:**
Option 1: Steam injection for 50% of the cooking time or 1 hour, whichever is longer
Option 2: Sealed oven for 50% of the cooking time or 1 hour, whichever is longer
Option 3: At least 90% relative humidity of at least 25% of the cooking time or 1 hour, whichever is longer
If you selected a time/temperature less than 145 °F plus applicable hold time, maintain relative humidity by selecting:
Option 4: At least 90% relative humidity of at least 25% of the cooking time or 1 hour, whichever is longer
For any time-temperature combination, if your product's total cooking time is less than 1 hour, maintain relative humidity by selecting:
Option 5: At least 90% relative humidity for the entire cooking time

Figure 1. Humidity Options from Revised Appendix A

provided clarification that defined a 5-log reduction of *Salmonella*, *Listeria monocytogenes*, and *Escherichia coli* O157:H7 as the target for shelf-stable products, which would include products such as dry cured ham and prosciutto. The document also discusses the agency's expectations for how processors should evaluate cooking deviations, post-processing handling and sanitation, and potential corrective actions for FSIS positive test findings. Concerning deviations, the agency clarified that during cooking, the come-up time from 50 to 130 °F should occur in less than or equal to 6 hours. A longer come-up time or interruption would constitute a deviation, requiring an assessment of the potential for growth and toxin production by *Staphylococcus aureus* and *Bacillus cereus*. If there is potential for 3 log of *S. aureus* growth, the agency expects the processor to test for staphylococcal enterotoxins and *B. cereus* emetic toxin.

The study by Goodfellow and Brown,[1] from which original *Appendix A* tables were derived, also investigated inactivation of *Salmonella* on the surface of beef rounds during dry oven roasting. The study determined that if steam was injected into the smokehouse for at least 30 minutes during cooking to an internal temperature of 130 °F, then a 7-$\log_{10}$ reduction could be achieved. The greater efficacy of moist heating compared with dry heating for inactivation of *Salmonella* is well established.[2–4] During convective heating, sufficient moisture by volume of air in the heating space can facilitate condensation on the surface of meat, resulting in moist heating. Conversely, in a heating vessel with low moisture by volume, evaporative cooling occurs as the moisture mass transfers out of the meat and into the air.[2] Ergo, FSIS had been concerned for several years about industry utilization of *Appendix A* time-temperature combinations without apparent regard to humidity within cook ovens. The importance of humidity in cooking, especially at mild temperatures, was further realized when a number of *Salmonella* outbreaks from jerky were attributable in part to

inadequate humidity during heating.[5,6] Since then, jerky heating was specifically addressed by FSIS in a 2014 compliance guideline, but until now, detailed guidance for all other products did not exist. FSIS has stated it has not changed the humidity recommendations within *Appendix A* other than "re-emphasizing" that they apply to all cooked products (including poultry), unless the establishment can support that humidity does not need to be addressed. Options for supplying adequate humidity to a process that relies on *Appendix A* time-temperature combinations were spelled out in the guidelines (Figure 1), and both attainment and accurate measurement of these humidity requirements are the primary concerns of industry.

For example, "impingement"-style ovens with continuous cooking have openings from which moisture and heat can readily escape, making it difficult to maintain humidity throughout a cook process. Also, some smokehouses in very small establishments lack dampers, and so humidity control would be impossible. Yet, the guidance states that measurement accuracy for cooking should include time ± 1 minute, temperature ± 1 °F, and humidity ± 5 percent. Further, it states that humidity "should be" part of Critical Control Points (CCP) monitoring of critical limits or prerequisite programs. Several types of products and/or cooking techniques are exempt from the humidity requirements and include:

- Immersion in cooking liquid medium
- Cook-in-bag
- Direct heat (e.g., grill, heating coil, flame, or rotisserie) due to rapidity of surface heating
- Semipermeable, impermeable product casing (such as frankfurters)
- Cooking beef patties (due to direct heat)

Revised Appendix B

"Stabilization" refers to cooling cooked meat and poultry expediently to delay the germination and subsequent outgrowth of spore-forming bacterial pathogens of concern, namely *C. botulinum*, *C. perfringens*, and *B. cereus*. The necessity of treating the cooling, or stabilization, control step in cooked meat and poultry processing as a CCP in USDA-FSIS-regulated establishments has been a point of debate for several years. Among some of the points made by industry scientists is that in 1998, FSIS overestimated by a very wide margin the number of surviving spores in meat and poultry products after cooking because the baseline data involved raw

Option Number	Applies To:	Cooling Parameters	What's New?
1	Fully cooked products (including intact or nonintact meat or poultry) and Partially cooked small-mass products, provided the establishment can support the heating come-up time to the final heating temperature for partially cooked small mass products is ≤ 1 hour. Products may be cured or uncured, although there is a larger safety margin if cured.	During cooling, the product's maximum internal temperature should not remain between 130 °F and 80 °F for more than 1.5 hours nor between 80 °F and 40 °F for more than 5 hours (6.5 hours total cooling time).	
2	Fully cooked products (including intact or nonintact meat or poultry). Products may be cured or uncured, although there is a larger safety margin if cured.	Chilling should begin within 90 min after the cooking cycle is completed. All product should be chilled from 120 °F to 80 °F in 1 hour and from 80 °F to 55 °F in 5 hours (6 hours total cooling time). Followed by continuous chilling until the product reaches 40 °F.	Previously, did not clearly indicate Option 2 applied only to fully cooked products. This option will be very challenging for industry due to the 120 °F to 80 °F in 1-hour stipulation.
3	Fully cooked products (including intact or nonintact meat or poultry) that are cured with: at least 100 ppm in-going sodium nitrite (either from a purified or natural source) and 250 ppm sodium erythorbate or ascorbate.	During cooling, the product's maximum internal temperature should not remain between 130 °F and 80 °F for more than 5 hours, nor between 80 °F and 45 °F for more than 10 hours (15 hours total cooling time).	
4	Fully cooked products (including intact or nonintact meat or poultry) that are formulated with ≥ 40 ppm sodium nitrite or its equivalent and a brine concentration of 6% or more, or formulated with or without nitrite (such as salt-cured product) but with a maximum water activity of 0.92.	During cooling, the product's maximum internal temperature should not remain between 120 °F and 40 °F for more than 20 hours, and the cooling process causes a continuous drop in product temperature or controls the product's temperature so that it does not stay between 120 °F and 80 °F for more than 2 hours.	Previously, Option 4 applied to products formulated with ≥ 120 ppm sodium nitrite or its equivalent and a brine concentration of 3.5% or more. Pathogen modeling programs have indicated these parameters would result in > 2-log *C. perfringens* growth, so the products have been removed.

Table 2. Four Options from Revised Appendix B *for Achieving Performance Standard for Cooling (≤ 1.0 log)*

meat and poultry samples analyzed by a method that had no prior heating step to destroy the vegetative cells, so the number of spores could not be differentiated and the colonies were not confirmed to be *C. perfringens* (RB Tompkin, personal communication). This led to very conservative time and temperatures being required for cooling in the 1999 version of *Appendix B* (i.e., no greater than a 1-log increase in *C. perfringens*). Several industry studies were subsequently published clarifying spore levels in raw meat and poultry samples, demonstrating growth control in actual meat and poultry products during extended cooling and die-off of vegetative cells of *C. perfringens* during subsequent refrigerated storage.[7–9] Indeed, the USDA risk assessment concluded that *C. perfringens* growth during stabilization of RTE or partially cooked (PC) meat and poultry products has a small overall effect on the likelihood of illness, and that growth during retail and consumer storage is the major predicted cause of illnesses from *C. perfringens* in RTE/PC meat and poultry products.[10] Although industry had contended that no outbreaks had been attributable to industrially produced meat and poultry products, FSIS cited in *Revised Appendix B* one outbreak associated with *C. perfringens* from commercially produced RTE turkey loaf product in 2000. The agency also took the opportunity to clarify a number of compliance criteria for heat-treated, not fully cooked products. FSIS acknowledged that food safety concepts associated with RTE products may also apply to heat-treated not-ready-to-eat (NRTE) products, such as ready-to-cook bacon.

"FSIS has provided much more detail than in previous versions of compliance guidelines for appendices *A* and *B*."

The revised document includes recommendations previously provided in *Appendix B*, FSIS Directive 7110.3, and examples of scientific evidence for establishments to support a safe production process. Several options for cooling meat and poultry products were provided, including requesting a waiver from regulatory performance standards to allow up to a 2-log multiplication of *C. perfringens* within a product, provided there's no growth of *C. botulinum*, if the establishment collects data from raw materials that demonstrate a relatively low level.

FSIS provided four recommendations for cooling now that limit growth of *C. perfringens* to be less than 1 log with no growth for *C. botulinum* (Table 2).

In an attempt to allay some of the industry concerns about achieving Option 2, FSIS published some recommendations for establishments that cannot meet the stabilization guidelines.[11] Recommendations included pre-chilling the cooler before loading product; increasing airflow (e.g., adding a fan) to speed cooling; and reducing the amount of product in each batch or lot placed in the cooler at one time to reduce the total heat load to be removed. Additional answers to public comments were provided pertaining to additional cooling options for establishments to use based on modeling.[12] The agency also published additional information and guidance pertaining to the use of Option 3 for stabilization of products containing natural sources of nitrite and ascorbate.[13,14]

FSIS outlines corrective actions for an establishment to consider when a cooling deviation occurs, including pathogen modeling. Growth of more than 1 log *C. perfringens* (or 2-log growth) and greater than a 0.30-log increase of *C. botulinum* would mean that product should be destroyed. The agency also recommended that processors assess *B. cereus* growth only if *C. perfringens* growth is estimated greater than 3 log. To aid product disposition determinations, product testing for *C. perfringens* should follow $n = 10$, $c = 2$, $m = 100$, and $M = 500$. Due to the work of Mohr and colleagues,[15] the compliance guideline clarifies that ComBase's Perfringens Predictor and the Smith-Schaffner models are most accurate for use in predicting growth of *C. perfringens* in meat systems. If evaluating existing or conducting new validation studies, the recommendations in the *FSIS Compliance Guideline: HACCP Systems Validation* should be consulted.[16] The types of scientific data that can be used for validation include in-plant data, modeling, challenge studies, and other regulatory/public health agency reports (e.g., Food Code, Canadian Food Inspection Agency, European Food Safety Authority, Codex).

Besides the industry concerns about *Appendix B* previously mentioned, there are additional concerns that the guideline contains general information that could be misleading. For instance, the guidance document cites from the U.S. Food and Drug Administration, "The minimum inhibitory salt concentration for *C. perfringens* is 7%, and 10% for *C. botulinum*." However, these limits are in growth media incubated at ideal temperatures. It's been reported that 3 percent salt completely inhibits *C. perfringens* in beef and ham during extended cooling for 21 hours.[17] Another term used is in reference to the use of peer-reviewed publications as scientific support for cooling. The guideline states that in order to use such scientific support as validation, processors must ensure that their cooling data "matches" that of the scientific support; however, there is no guidance or definition as to what constitutes a suitable match. Another such phrase concerning scientific references is that "if establishment does not follow all parts," then the scientific reference may not be applicable. The term "all" could be misconstrued such that no scientific reference would be suitable and that every process would need to be validated by conducting a laboratory-scale or pilot-scale study or in-plant validation with surrogates. This would be unduly cumbersome and costly to industry, and small and very small establishments usually lack the resources to perform such work. The guidance mentions that "critical operating parameters" need to

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be predefined. This is of course helpful, but these types of phrases will surely lead to much debate about what is and what is not "critical" between in-plant personnel of FSIS and food company personnel attempting to explain their scientific support and validation for cooling.

Future Revisions Likely

FSIS has provided much more detail than in previous versions of compliance guidelines for appendices *A* and *B*. The agency has taken an approach toward these guidelines of trying to refine and improve upon their technical accuracy and utility for industry and in-plant personnel. FSIS has been open to industry and academic input on ways the guidelines can offer flexibility and still ensure pathogen control. For instance, an industry expert on cooking has proposed the use of wet-bulb temperature as a suitable means to ensure adequate moist heating of meat product surfaces in lieu of the humidity measurements or minimum steam injection requirements (B Hanson, personal communication). What is most clear is that FSIS is willing to accept suitable scientific support for the safety of meat cooking and cooling processes in the form of challenge studies, predictive modeling, in-plant data, and other reliable sources. Therefore, the need to rely on safe harbors in appendices *A* and *B*, and the now more prescriptive qualifying criteria for using such safe harbors, should nudge industry to seek its own scientific validation of customized processes. For cooking, newer, more accurate thermal inactivation data for *Salmonella*, Shiga toxin-producing *E. coli*, and *L. monocytogenes* have been collected in roast beef, turkey, and ham.[18] Such data could form the scientific basis for a cook process instead of *Appendix A*, especially when used in conjunction with the process lethality spreadsheet.[19] Similarly, a number of scientific studies demonstrate control of growth of *C. perfringens* as a result of product formulations. Matching the critical operating parameters of such scientific data to those of an industrial process is necessary to consider the process or product validated, but in many instances, that may be easier than meeting the current stipulations of the safe harbors in the compliance guidelines for appendices *A* and *B*. ■

"The revised document includes a definition of pasteurization and guidance on how to label products as pasteurized."

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be adhered to? These are the pressing questions, whether or not a cage-free shift is in the future of the egg industry.

Food Safety Culture

Ultimately, it all boils down to the egg producer's food safety culture. You can have the best, most expensive processing equipment the industry has to offer and allow your free-range chickens to frolic in fields of beautiful St. Augustine grass. None of that will be enough to keep the consumer safe from foodborne illness if you have a poor food safety culture. Does your egg processing facility have sound biosecurity controls, pest controls, proper cleaning and sanitizing, and proper temperature holds? Without these, nothing else matters. In the end, there really is no mystery. The industry has had the tools to make our eggs safe all along. ■

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SNACK FOODS

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as "handcrafted, using only the finest ingredients" and "hand-cut like it should be." Hand-cutting animal proteins allows for various thicknesses (even within the individual slices), causing the standard dehydration process to produce different levels of water activity measured in the end product. But indulging in artisanal jerky because it is touted as a healthy, high-protein, gluten-free, and low-calorie snack does not reduce the concern of possible pathogen growth if the jerky is not processed safely.

Validation of Procedures

A very important aspect of food safety, even with snack foods, is validating one's procedures by looking at previous studies to see if the procedures are actually effective at slowing down or killing pathogens (see "*Salmonella*-Tainted Cereal," p. 55[10–14]). For example, a cookie producer might ask if the heating process is enough to kill the *Salmonella* from the eggs or flour. Also, validating the sanitation procedures for specific food types and manufacturing processes is an important step toward keeping snack foods safe and consistent in quality. Updating validation studies on a regular basis ensures that current technology and science are understood and implemented in the processing procedures. What worked 20, 15, 10, or even 5 years ago may not work in the current food safety and quality environment.

Snack Foods for Busy Lives

Snack foods are an established part of life. They have even become a popular meal replacement for many individuals on the go. As this market sector continues to grow and expand in unique flavors and food offerings, one thing is clear: Pathogens will find a way to survive in this food segment. Food safety and quality experts need to stay diligent, because the expectation, or more likely the assumption, of the consumer is that any food sold in retail is safe to eat. ■

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ing this approach will help meet regulatory requirements and give the food manufacturer confidence that the products they are making are wholesome and safe for consumption. ■

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equipment and lines to prevent the recontamination of already-cleaned equipment. When many sanitors are involved in cleaning a production line, they need to be coordinated to be on the same step at the same time. For example, when cleaning adjacent equipment, if one of the sanitors is ready to move to step four while the others around him are still at step three, there is a risk that the others at step three will recontaminate the equipment; ideally, the sanitor ready to move to step four should help his teammates to keep everyone cleaning adjacent equipment synchronized. If synchronization of the steps is not possible or if adjacent lines are still running product, steps need to be taken to segregate the lines, such as hanging tarps, using dikes to control water flow, or controlling the direction of the cleaning tasks and the discharge of air and water.

The last element we will touch on is periodic equipment cleaning (PEC). This is defined as periodically disassembling a complex assembly not disassembled during normal cleaning but that could be a harborage point for microbes and insects. To assist with the identification of difficult-to-clean areas, an equipment design checklist can be used by maintenance and sanitation. A frequency will need to be established and SSOPs written to define the task and provide clear instructions to all technicians and sanitors. We cannot stress enough the importance of a PEC program to prevent microbial contamination and infestation.

Conclusion

To conclude, continuous improvement of the sanitation practices and hygienic design of bakeries cannot be accomplished by one group alone. To redesign equipment, OEMs should be working with their customers and with many of their customers' departments (engineering, production, sanitation, maintenance, safety, etc.) to obtain feedback during the design and building phases. Involving only a few of the departments is likely to lead to further modifications after the equipment is built, adding cost and time to the delivery. The same goes when equipment is scheduled for rebuild or modifications by the bakery; different departments should be working together to improve hygienic design and cleanability that will further improve sanitation efficiency and effectiveness, and, most importantly, reduce risks that could harm consumers.

In addition, sanitation teams should be working together during the cleaning and sanitizing process to prevent cross-contamination and identify opportunities to improve sanitation practices. ■

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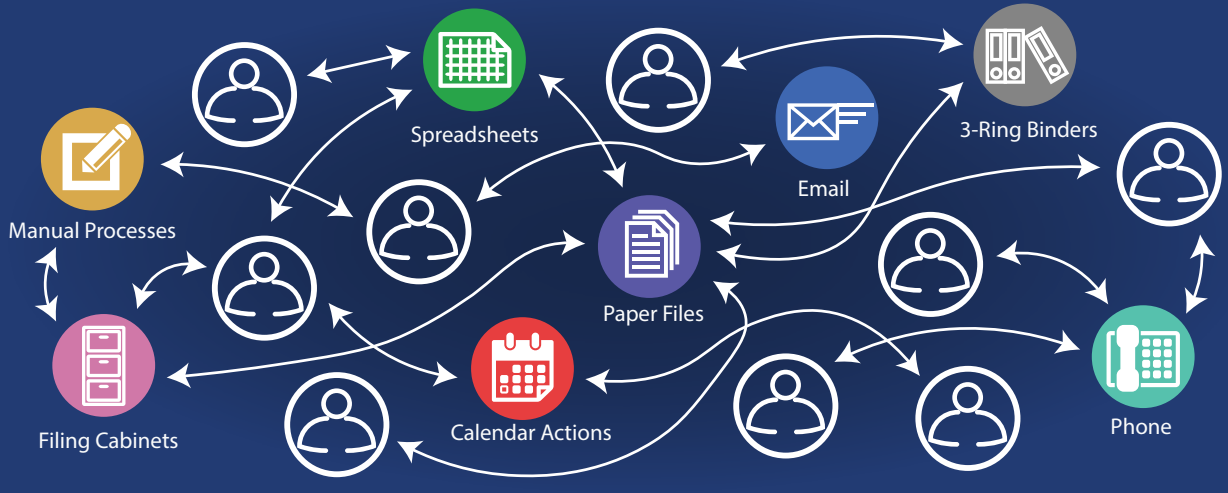

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