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## FSMA's GMPs: ARE THEY THE RIGHT MOVE?

Strategizing how to block the risk of  
cross-contamination with the proper GMP pieces in play





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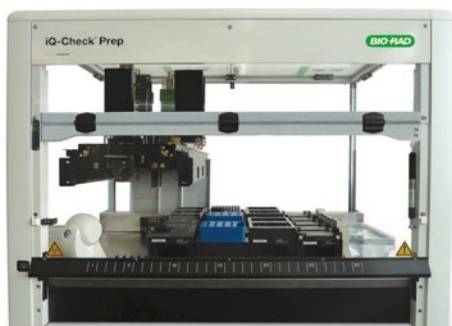
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#### CORRECTION

In the PEMP Decision Tree diagram for the "Components for an Effective Pathogen Environmental Monitoring Program" article, page 35, February/March 2014 issue, the two lower right hand boxes were mistakenly reversed. A corrected version of the diagram/article is available at [www.foodquality.com](http://www.foodquality.com).

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# From The Editor

**T**he *Economist*'s March 15<sup>th</sup> article, entitled "A La Cartel: Organized gangs have a growing appetite for food crime," takes a look at the increased number of criminals turning their attention to food fraud activities. Some crooks who even once focused on drugs have switched to food due to the potential of better profits, as the article points out, "Not everyone is a junkie, but everyone buys food and drink."



Unlike food defense, the intent of food fraud—which includes economically motivated adulteration (EMA)—isn't to harm; nonetheless, it may damage public health as the related health risks are often more risky than the traditional food safety hazard because the contaminants are unconventional. Food fraud can be committed through various methods, such as dilution, substitution, mislabeling, counterfeiting, etc.

The awareness of food fraud has recently grown due in part to last year's various meat scandals (horse, rat, donkey) that occurred across the globe. So what is industry doing to combat this emerging problem?

The issue of food fraud prevention was one of the main topics discussed at this year's Global Food Safety Conference in Anaheim, Ca., where several members of GFSI's Food Fraud Think Tank emphasized that an effective detection and deterrent strategy doesn't mean *more* testing, but "SMART" testing: Specific, Measurable, Assignable, Realistic, and Traceable. The group also discussed the importance of understanding vulnerabilities in order to achieve prevention. The Think Tank created two new proposed elements for inclusion in version 7 of the GFSI Guidance Document, which includes identification of risk through a vulnerability assessment followed by the creation of a vulnerability control plan to provide mitigation methods.

Framework for vulnerability assessment is also under development by USP. In the meantime, the organization's Food Fraud Database is available. This searchable database includes fraud history by ingredient, available detection methods, and potential hazards. There's also the NCFPD EMA Incident Database. In addition, NCFPD is collaborating with USP to evaluate the EMA vulnerability of the 1,100 monographs in the *Food Chemicals Codex*, a collection of quality and purity specifications and methods for food ingredients.

As the Think Tank stated, when it comes time to identify your own company's food fraud vulnerabilities, the best strategy to have is to think like a criminal.

**Marian Zboraj**  
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# LETTERS TO THE EDITOR

## FDA Inspections in 2014 FEBRUARY/MARCH ISSUE

FDA's excuse in not completing the promised number of plant inspections due to the budget is a typical bureaucratic explanation. How can they spend so much money to inspect one foreign food plant? Do they think the inspection trip is their luxurious vacation trip? Because they don't know the culture, area, people, and language, they hire an interpreter and take so much time to finish one plant—making more money for them. Why does FDA not hurry to establish third-party auditor system? Furthermore, in the U.S., there are many able foreign-born U.S. citizens who can understand the culture and language of the foreign countries that FDA wants to audit. By hiring and training them as an inspectors, we can save lots of money. The best solution is to hire the retirees from

the U.S. food plants who worked as QA/QC managers, in R&D, and as food chemists. With a little training, they can perform much better than newly hired inexperienced FDA inspectors.

—Kuen Lee, food safety manager retiree, Unilever

## Brand Protection in a Social Media Age FEBRUARY/MARCH ISSUE

They [Don and Adrian] make great points. In addition, social media can be used to share best practices within industry to improve our food defense strategies. The Food Defense Strategy Exchange LinkedIn group is a great case in point. I think our own blog, currently in a series about the proposed intentional contamination rule, is another case in point.

—Ned Mitenius, senior consultant, Periscope Consulting



## Fingerprinting Food FEBRUARY/MARCH ISSUE

Nice article, however NIR is an older technology, and may not catch everything. Try looking at [https://en.wikipedia.org/wiki/Hyperspectral\\_imaging](https://en.wikipedia.org/wiki/Hyperspectral_imaging). The USDA has spent a great deal of time, money, and effort in developing this hyperspectral technology and are happy to provide the Research and Development data to implement this detection equipment.

—Steve Baryschpolec, consultant, Compliance-Engineering

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#### ■ AOCS Official Method Cd 29c-13

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# NEWS & NOTES



## Global Food Traceability Center Strengthens Seafood Industry

The Institute of Food Technologists Global Food Traceability Center has received a grant to conduct research into the impacts of traceability on consumer attitudes and business performance in the seafood industry from the Gordon and Betty Moore Foundation. The purpose of the project is to strengthen the performance and proficiency of the seafood industry by providing knowledge about the impact of traceability on reduction of waste, enhancement of consumer trust, and increase of business efficiencies. Additionally, the project will deliver a software application that can be used by stakeholders seeking to better understand their return on investments in traceability solutions.

## Improving Cheese Ripening Processes

A new E.U.-research project, SMARTRIPE, aims to bring a number of improvements in cheese ripening technology by adopting sequential ventilation procedures and a new monitoring concept in cheese ripening rooms. The SMARTRIPE project builds on the results of previous FP6 TRUEFOOD project on cheese ripening. These results proved the concept of “sequential ventilation” as a mean to save around 50 percent of energy consumption in ripening rooms, and defined strategies to control cheese mass loss (cheese water evaporation) while preserving cheese quality attributes. This two-year research project funded by the Seventh Framework Programme of the European Commission aims to develop a new technology for cheese ripening.

## FAO Expands Food Security Knowledge

More than 220 universities in Latin America and the Caribbean are joining the Food and Agriculture Organization (FAO) to expand learning opportunities and improve policies for food security. With the support of the European Union, FAO has signed a Memorandum of Understanding with the Association of Universities of Latin America and the Caribbean to develop the education program. The initiative will offer a new Master's program in Food Security, in addition to elearning courses currently offered by FAO. The partnership will target current and potential policymakers in the region. Rollout of the new courses is slated for January 2015.



## Updated FDA Requirements for Infant Formula

FDA's interim final rule amends the FDA's quality control procedures, notification, and record and reporting requirements for manufacturers of infant formula products. The rule, in part, will ensure that infant formula contains all federally required nutrients. It also establishes cGMPs specifically designed for infant formula, including required testing for microbial contamination. This microbial testing includes testing representative samples of finished products to prevent the distribution of products contaminated with the pathogens *Cronobacter* and *Salmonella*. The rule also establishes quality factor requirements to support healthy growth. Applying only to formulas for healthy infants, the rule is accompanied by two draft guidance documents for industry, including one document that addresses the manufacture of formula products made for infants with unusual medical or dietary problems, such as infants who are born extremely premature.

## Americans Want More Government Oversight for Food Safety

The Harris Poll of 2,236 adults surveyed online indicates that strong majorities of U.S. adults say food recalls have them at least somewhat concerned (86 percent with 58 percent somewhat concerned and 28 percent seriously concerned) and believe there should be more government oversight in regards to food safety (73 percent). When those who think there have been more food recalls lately are asked who they hold most responsible for this increase, the highest percentage by a dramatic margin place the blame on those responsible for packaging and/or processing food (50 percent), though the federal government (19 percent) and those responsible for growing and/or raising food (16 percent) also received blame.

## Business Briefs

**Shimadzu Scientific Instruments** opens new Shimadzu Solution Center at its North American headquarters in Columbia, Md.

**Covance** expands its nutritional chemistry and food safety services with a new 10,000 sq. ft. laboratory this summer within its existing facility in Harrogate, England.

**SGS Food Safety Services** opens new ISO 17025 accredited food testing laboratory in Fairfield, N.J.

**Universal Pasteurization** purchases the assets of high-pressure processing services provider **GL Foods of Coppell**.

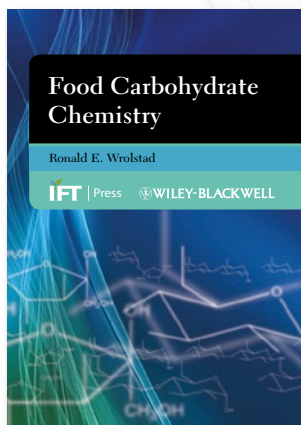
**It'sFresh! Inc.** expands to a new headquarters in Eden Prairie, Minn.

**ProcessPro**, a mid-market ERP software solution company, has become a member of the **Northwest Food Processors Association**.

**The American Institute of Baking** enters into an agreement to acquire **Beijing Sino-Swiss ADC Service**, an officially approved certification body in Beijing, China.

# KEY RESOURCES

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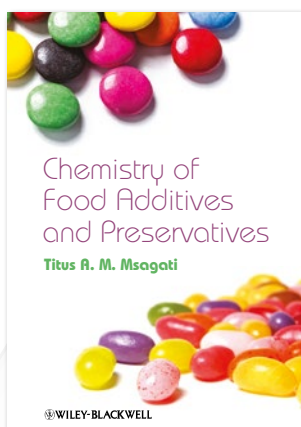


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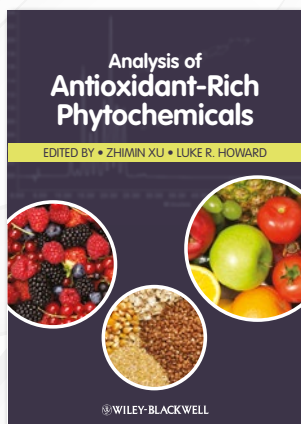


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Zhimin Xu, Luke R. Howard

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# Washington Report



## Will FDA's New Budget Cover Food Safety Costs?

Examining how FDA's budget request for Fiscal 2015 will affect FSMA implementation, FDA inspections, industry user fees, and more | BY TED AGRES

**F**or Fiscal 2015, which begins October 1, the FDA is requesting \$1.48 billion to support food safety activities, a \$263 million (22 percent) boost over current year levels. Of this amount, \$253 million would be directed to implement provisions the Food Safety Modernization Act (FSMA). But only \$24 million of that would be provided by public taxpayer funds with the lion's share of \$229 million coming from industry user fees, including proposed new fees for food import and food facility registration and inspection.

President Obama released his Administration's Fiscal 2015 budget request on March 4. FDA's total budget comes to \$4.74 billion, a \$358 million (8 percent) increase of over Fiscal 2014. Of the total, \$2.58 billion would come from public funding and \$2.16 billion would be obtained from new and existing user fees, imposed mostly on manufacturers of prescription and generic drugs, medical devices, and tobacco products. New and existing food industry fees constitute a smaller but rapidly growing portion of these assessments. Overall, more than 93 percent of FDA's \$358 million increase comes from industry user fees, which would jump by \$335 million or more than 18 percent, while the agency's public support would increase by only \$23 million or less than 1 percent.

The agency's overall increase "is really quite a positive outcome for FDA in this tight budget environment," said FDA Commissioner Margaret A. Hamburg, MD, in a statement accompanying the budget release. "I consider the additional funding for the agency to be a tribute to the important work FDA performs on behalf of the American people, the hard work and dedication of FDA employees, and our ability to meaningfully demonstrate the value of our work to stakeholders."

FDA says the proposed food safety increase will allow it to focus on five main activities: rulemaking and guidance development to support regulatory action; technical support to ensure safety standards are effective and efficient; food safety regulatory training and capacity among stakeholders and partners, including federal, state, local, tribal, and international entities; risk analysis to support priority setting; and research to better understand the impact of antimicrobial resistance on public health.

### 'Insufficient Funds'

FDA's proposed increase "looks trivial compared with the resource needs for FSMA implementation," says David Acheson MD, president and CEO of the Acheson Group LLC and a former FDA associate commissioner for foods. "And

this is not just about more inspections. It is about having the resources to raise awareness around FSMA and training for inspectors so they fully understand FSMA," Dr. Acheson tells *Food Quality & Safety* magazine.

Having sufficient funding for FSMA is essential. "Without adequate funding, FDA will be unable to adequately fulfill its oversight responsibilities," said Michael R. Taylor, FDA deputy commissioner for foods and veterinary medicine, in congressional testimony earlier this year. "This includes implementing the Foreign Supplier Verification Program, which requires new staff and skills to audit and verify the adequacy of the importer's verification plan; conducting more foreign inspections; working more closely on food safety with foreign government to leverage their efforts; and improving our data and import systems to facilitate prompt entry of foods that meet our safety standards," Taylor told the House Committee on Energy and Commerce Subcommittee on Health in February.

When FSMA was signed into law in January 2011, the Congressional Budget Office estimated that FDA would need more than \$580 million in additional funding to implement the law's requirements. Last year, the Department of Health and Human Services, FDA's parent agency,



lowered that estimate to \$400 million to \$450 million based on different assumptions and a commitment to efficiency. To date, FDA has received \$78 million for FSMA, an agency spokesperson tells *Food Quality & Safety*.

### Boost in User Fees

The proposed new user fees include a \$169 million food import fee and a \$60 million food facility registration and inspection fee. The import fee would target activities associated with implementing the Foreign Supplier Verification Program, which includes recruiting and training FDA import staff to assess the adequacy of importer supply chain management and verification programs. The agency says it will also invest in the staff, information technology, and process improvements needed to make timely import entry decisions. "These fees will enhance both the safety protections for imported food and feed and the efficiency and speed of food and feed entry decisions, thus supporting international trade in safe food and feed," the agency says in its "Justification of Estimates for Appropriations Committees."

Under FSMA, firms are required to renew and update their registration information every two years. In addition, all "high-risk" domestic facilities must be inspected by 2016 and no less than every three years afterwards. The law directs FDA to inspect at least 600 foreign facilities annually and double those inspections every year for the next five years. Despite deficiencies in its database systems, FDA had been aiming to inspect all foreign and domestic high-risk facilities within three years, two years earlier than directed by FSMA, and is attempting to inspect all non-high-risk facilities within seven years, according to the agency's "2013 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices" released last November.

The new food facility registration fee would be used to upgrade FDA's inspection system "by increasing the effectiveness of inspections through adoption of preventive controls, training of personnel to inspect against the new prevention standards, and developing new ways to educate and inform industry," the agency says. The fee would also support improvements in food and feed safety science and risk analysis, "so that knowledge of the

methods of food and feed contamination can better prevent outbreaks and ensure that resources are better focused on areas of greatest risk."

Authorization to impose the new user fees will require passage of new legislation, something that is far from certain. The FDA's Fiscal 2014 budget request had also proposed the facility registration and import user fees. In his February congressional testimony, Taylor said the registration fee would allow FDA to increase its capacity to establish an integrated national food safety system "and further strengthen food safety inspection, research, and import review." The proposed import user fee would assess a "minimal amount (approximately \$20)" per line entry, defined as each portion of an imported shipment that is listed as a separate item on an entry document. "The improvements to the import process with not only facilitate the entry of safe products, but also improve public health by enabling FDA to focus its attention on higher-risk products," Taylor said.

If the new user fees are approved and enacted next year, FDA will use the funds for comprehensive retraining of federal and state inspectors to ensure inspection quality and consistency; training and technical assistance for small and mid-size growers and processors; and building the import oversight system mandated by FSMA. "A central theme of these investments is supporting and leveraging the food safety efforts of both public and private partners to make the most effective use of available resources," the agency says in its congressional justification.

But Dr. Acheson is skeptical that Congress will give FDA the green light. "Once again the FDA has asked for user fees, and they did not get them the last several times, and they will not likely get them this time, either," he says. "The last several budgets have also had amounts for re-inspection fees, but as far as I am aware the FDA has not put the system in place to collect any of those. Maybe that is a 'Catch-22' in that they don't have the resources to put the system in place to collect the resources they so desperately need," Dr. Acheson says.

Indeed, the current year's \$15 million food reinspection user fee would be cut to \$6 million in Fiscal 2015, while a current \$13 million food recall fee would

drop to \$1 million. The already authorized Voluntary Qualified Importer Program, which is intended to expedite imports from certified foreign suppliers and importers, would collect \$5 million in new user fees starting next fiscal year. In addition, FDA is requesting a new \$5 million food contact notification user fee "to better position FDA to reduce microbial food contamination through premarket notification to ensure the safety of food contact substances."

In a related area, the Fiscal 2015 budget request for USDA's Food Safety and Inspection Service, which provides federal inspection of domestic meat, poultry, and processed egg products establishments as well as inspection of imported meat, poultry, and egg products, would remain relatively flat at around \$1.0 billion. The budget anticipates implementation of "modernized poultry inspection practices," including efficiencies through the rollout of the Public Health Information System to states, resulting in more streamlined administrative and scheduling processes, USDA says in its budget document.

### Budget Outlook Murky

Traditionally, release of the president's annual budget request marks the start of the congressional appropriations process, with committees in the House and Senate holding hearings on agencies under their jurisdictions. But it's been five years since Congress has passed a budget this fashion, with legislators having largely ignored the White House's proposals. The situation is further complicated this year because Congress has already agreed to two-year federal spending levels through a budget deal spearheaded in December 2013 by House Budget Committee Chairman Rep. Paul Ryan (R-WI) and Senate Budget Committee Chairwoman Sen. Patty Murray (D-WA).

In fact, Murray announced in February that Senate Democrats would not bother passing a budget this year because "it wouldn't be productive to relitigate it so soon after our two-year deal." Ryan has said that Republicans in the House would wait to see Obama's budget request before beginning the process of crafting a "balanced budget" of their own for FY 2015. ■

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# Industry Insights



## Do Meat and Poultry Handling Labels Really Convey Safety?

In the wake of the Jack in the Box *E. coli* outbreak 20 years ago, the USDA mandated food safe handling labels on packages of raw meat and poultry to educate the general public—however, the information on the labels may have been incomplete from the start | BY **DARIN DETWILER, M.A.ED.**

Only weeks after the Clinton administration and new Agriculture Secretary Mike Espy took office in 1993, the USDA initiated a public education program in response to the Jack in the Box *E. coli* outbreak that hit the Pacific Northwest. The USDA wanted to ensure that the public understood not only how to handle raw meat and poultry products safely, but also how to properly cook it. Families at home, as well as cooks at restaurants, needed to be brought up to date with more accurate cooking temperatures.

Washington state law, at the time of the outbreak, required restaurants and institutions to cook hamburger patties to an internal temperature of 155 degrees Fahr-

enheit, whereas the federal standard was only 140 degrees Fahrenheit. According to a 1995 article in the *Spokesman Review* (Spokane, Wash.) newspaper, Bert Bartleson, technical expert for the state health department's food program investigating the outbreak stated that "had Jack in the Box followed state regulations, which mandated that hamburgers be cooked to an internal temperature of 155 degrees, the [1993] epidemic would have been prevented." He also pointed out that "State law [of 155 degrees] superseded a federal guideline at the time of 140 degrees... Either [Jack in the Box] didn't believe in science, or they didn't read the literature. If they followed the standards...no one would have gotten sick." The FDA and USDA have since revised federal require-

ments, increasing cooking temperatures for raw meat to 155 degrees.

Many have called the 1993 Jack in the Box *E. coli* outbreak the "9/11 of the meat industry." This multistate event went far beyond just some people getting sick. According to the CDC, the state health departments of Washington, Idaho, Nevada, and California received reports of over 600 cases. Approximately 150 people were hospitalized, and of those 37 developed Hemolytic Uremic Syndrome, and of those four young children died, including my 17-month-old son, Riley.

The day I buried Riley, I stood there with so many questions and such a rage inside. Only months prior, I was operating a nuclear reactor on a Navy submarine—I had never heard of *E. coli*. How did this happen to my son, to my family, to the American consumer? How could this be prevented from ever happening again?

Espy proclaimed that, in the absence of a way to detect or prevent the presence of the bacteria, the USDA must do "everything [it] can do to help inform consumers about proper preparation and storage of not-ready-to-eat meat and poultry." In the wake of the outbreak, the USDA's new Pathogen Reduction Program included a consumer awareness portion described as a "bold action" to educate the general public. The program included the mandated use of Food Safe Handling Labels affixed to packages of raw meat and poultry. For the last two decades, this has been the most visible device the USDA has employed to educate consumers about food safety as the USDA requires these instructions to be displayed on all packages of raw (or not-ready-to-eat) meat and poultry sold in the U.S. Unfortunately, I believe that the information on these labels was incomplete from the start.

In a 1993 discussion with Espy, I specifically asked why the cooking information was vague. He responded that because meat and poultry have different cooking temperatures, having those different temperatures listed may lead to confu-

sion on the part of the consumer. He also stated that if there were different labels to be applied to different kinds of meat, mislabeling could occur at the plant or at the grocery store.

I left that meeting with a want to learn more about the kinds of cooking messages that they had previously used. Through some USDA contacts in D.C., I was able to find a 1990 Food Safety Inspection Service fact bulletin in which the USDA simply stated:

*“Cook meat and poultry thoroughly—meat to at least 160 degrees Fahrenheit, and poultry to at least 180 degrees Fahrenheit. Using a meat thermometer is the best way to ensure that large cuts of meat are done. Greyish color and clear juices show when patties and individual pieces are done.”*

This warning indicated that more detailed information can be put out in a simple, precise way that would not require different labels for many products. Why didn't the USDA use this? Jeremy Rifkin, then the leader of a consumer coalition group called Beyond Beef, criticized the USDA on this as he stated how the information was insufficient, thus creating a weak message. His group even demanded that “Cook thoroughly” be replaced with more explicit instructions.

Though many newspapers across the country reported that the USDA's decision was motivated by the 1993 *E. coli* outbreak, there was one more motivating factor for their decision. In May of 1993, the government agreed to require the Food Safe Handling Labels as part of its settlement of a lawsuit filed by the Beyond Beef coalition in Washington, D.C.'s U.S. District Court. The creation and mandates of the labels were not so much a result of the goodness of the USDA as they were part of a judicial order required by the department to carry out.

On October 14, 1993, one day before the initial rule of the labeling was to take effect, the National American Wholesale Grocers Association convinced a Texas federal judge to issue an injunction to delay the labeling because “unlabeled meat was not a significant health threat, and that the tainted meat outbreak in January was isolated to the Pacific Northwest.” Ironically, though sad, only two weeks later, the Texas State Department of Health issued a statewide warning similar to the one contained

in the USDA's intended Food Safe Handling Labels because of the deaths of two 3-year-old Texas boys from *E. coli*.

Though some stores voluntarily labeled their meat packages, the required labeling did not start until May 27, 1994—and even then, only ground meat products required labeling. All other meat and poultry products required labeling as of July 6, 1994. According to the Pathogen Reduction Program's description of consumer awareness in the Federal Register, the Food Safety and Inspection Service (FSIS) will “inform consumers of the risks associated with unsafe food handling.” However, in order to get the federal judge to release the injunction, the labels had to be designed in such a way that they would state proper handling techniques, but not any health hazards.

*“This product was inspected for your safety. Some animal products may contain bacteria that could cause illness if the product is mishandled or cooked improperly.”* This message does not warn consumers of the possible dangers associated with meats in general. Instead, the issue is now discussed in terms of a public health, not an industry or USDA, problem.

I was dissatisfied that the labels do not identify any potential hazards. Neither *E. coli*, nor any other foodborne pathogen is named on the labels. I was not surprised that the labels don't explain how the bacteria get into the meat in the first place. What angered me the most, however, was that the labels do not describe the severity or the consequences of the problem to consumers. While I focused on the fact that words such as “may” and “could” make the problem sound insignificant, I also understood that not every package of meat will be contaminated. I had already been unwillingly dragged into the meat version of the game Russian Roulette—I knew far too well that there is a great difference between something that “could cause illness” and something that could cause toddlers to suffer and, in too many cases, die.

The lesson I learned next, however, was something that has been one of the most painful elements of the tragedy of my son's death that I have carried for the last two decades. Work with the USDA relating to educating consumers was thwarted by the efforts of the industry and the dual responsibilities of the USDA. Some of the department's administrators and assis-

ants expressed concern over the pressures associated with the labels and with public awareness in general from within the industry, as some meat groups feared that an educated public would stop buying their product. Even the USDA was apprehensive of giving the consumer too much information as the consumer may not only be motivated to stop old behaviors associated with the products, but be motivated to discontinue purchasing the product as well. This highlights an inherent conflict of interest for the USDA, for its charge is not only to regulate the quality of meat, but also to promote the sale and use.

According to a spokesperson for the American Meat Institute, “Warning labels really frighten the public, if consumers follow safe handling procedures, there's no need to scare people about what is really a very wholesome and nutritious product.” This description of the clean product may be very easy for the general public to believe, but what if a product is contaminated? In its 1990 FSIS fact bulletin, the USDA described contaminated meat and poultry as causing “thousands of individual cases, hundreds of outbreaks, and several deaths each year.” The USDA went on to report “6.5 – 8.1 million Americans may actually suffer [foodborne illness] symptoms each year.” Mind you, this statement was made in 1990—four years before the USDA declared *E. coli* as an adulterant and well before reporting of illnesses from many food sources, let alone the systems to report, record, and monitor were in place.

Perhaps by placing a weak message on the labels, the USDA was at least able to mandate that some form of food safe handling instructions be placed on every package of meat and poultry sold in the U.S. for the last 20 years. But requiring labels and enforcing their use is two different things. I have visited plenty of grocery stores with their own butcher and packaging stations in which labels were not used on the products. ■

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**Detwiler** is a graduate lecturer on the economic and social aspects of food at Northeastern University. In the 1990s, he worked with USDA in the early days of their Pathogen Reduction Program to gain the federal regulation of food safe handling labels on meat. He holds an FDA certification as a food science educator and served two terms as a USDA regulatory policy advisor on the National Advisory Committee on Meat and Poultry Inspection. Detwiler continues to consult about the history of food safety legislation and can be reached at [d.detwiler@neu.edu](mailto:d.detwiler@neu.edu).





# FSMA's GMPs: ARE THEY THE RIGHT MOVE?

Strategizing how to block the risk of cross-contamination with the proper GMP pieces in play

BY VIRGINIA DEIBEL, PHD, AND TIM LOMBARDO

The FDA has announced, or perhaps admitted, that the current Good Manufacturing Practices (cGMPs) as outlined in 21 CFR 110 do not adequately address the safety issues associated with the manufacturing, processing, packing, or holding food products. Indeed, “high-profile outbreaks of foodborne illness...strick(ing) one in six Americans each year have caused a widespread recognition that we need a new, modern food safety system that prevents food safety problems in the first place.” The FDA, through the proposed Food Safety Modernization Act (FSMA), is attempting to decrease risk by imposing regulations on how facilities manage their food safety systems.

They have data to suggest that governmental oversight is helpful. For example, between 1976 and 1997, the average size of a *Listeria monocytogenes* outbreak was 53.8 cases. After PulseNet, between 1996 and 2004, the average outbreak involved 21.5 cases and with the CDC *Listeria* initiative in conjunction with PulseNet (2004 to 2008), the average outbreak was reduced to 7.2 cases. These data suggest that increased surveillance decreased food safety cases in the U.S. from 1976 to 2008. Why then are there still multistate outbreaks that include numerous deaths, as in 2011 when the largest *Listeria* outbreak occurred due to contaminated cantaloupes that sickened 1,476 and killed 33? The fundamental question is this: Will GMPs included in FSMA be enough to control the risk of cross-contamination for hazards in food manufacturing?

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## FSMA Proposed Revisions

The FSMA changes would require facilities to have a written Food Safety Plan to include the following elements: a risk-based hazard analysis, preventive controls for hazards determined to be reasonably likely to occur, monitoring, corrective actions, verification, and associated records and documentation.

Concomitant to a risk-based hazard analysis, proposed FSMA regulations also state that there must be formalized and documented supporting preventative control programs that reduce or eliminate identified hazards. Hazard plans are only the start of a food safety process because they merely outline the hazards and controls to minimize or reduce their risk. Once the hazards have been identified, it is incumbent upon the plant to devise preventative control programs to address activities of the manufacturing process that can reduce or eliminate them. These programs, outlined in FSMA include Manufacturing Process, Allergens, Sanitation, and Recall. It is also stated that the facility must develop “other” programs “as needed.”

## Proposed cGMPs

While FDA is not specifically requiring cGMPs as a Preventive Control Program (at this time), subparts of the current 21 CFR 110 may be redesignated and included in 21 CFR 117. Primary proposed provisions include programs that address: allergens, personal hygiene, plants and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, warehousing and distribution, and employee training.

While these specific cGMPs are outlined, the challenge to plants will be to fill in the outline with a detailed program that is thorough and designed specifically for the plant, product produced, equipment used, plant condition and layout, and workforce followed by verification of the outcome, scientifically, for efficacy. How can this be done? The short answer is to learn from past and shared practices that have been already proven based on the principle that food safety is not competitive. The long answer is to try something (anything) and do not stop until the system is proven to be effective through a rigorous verification process (environmental monitoring program, allergen testing program, visual inspection system, metal detection, etc.). So where do we start? For the purposes of this article, we will focus on food safety as it relates to microbiology, since it is one author’s specified training.

First, the principle of cross-contamination must be conveyed to production, sanitation, maintenance, and quality assurance employees. Cross-contamination relative to microorganisms, allergens, chemicals, or extraneous matter is the act of transferring an item from one place to another. Cross-contamination can occur through different methods (see Table 1).

Secondly, include an environmental monitoring system that has a site list consisting of product contact (Zone 1), non-contact (adjacent to product contact; Zone 2), and indirect contact (floors, motors, chain drives, walls; Zone 3) for *each* piece of production equipment and test all vehicular traffic and traffic ways into/out of a post-lethality and/or exposed product production room. Additionally, the program is to include *specific* activities to be conducted when there is an out-of-specification result, such as an investigation by a multifunctional team, and implement corrective and preventative actions. A corrective action is an activity

Vehicle	Method
Air	<ul style="list-style-type: none"> <li>■ Air hoses</li> <li>■ Vents</li> <li>■ Fans to cool workers</li> <li>■ Cooling units</li> </ul>
Water	<ul style="list-style-type: none"> <li>■ Sanitation hoses that are &gt;40 psi</li> <li>■ Drain backups</li> <li>■ Roof/door leaks</li> <li>■ Leaking hoses and pipes</li> <li>■ Equipment</li> </ul>
Direct Contact	<ul style="list-style-type: none"> <li>■ Forklift tires or any vehicular traffic leaving a production room and re-entering</li> <li>■ Shoes coming in from the exterior of a production room into the production room</li> <li>■ Pallets</li> <li>■ Employee gloves, aprons</li> <li>■ Dust (especially during construction)</li> </ul>

Table 1: Cross-Contamination Vehicles and Methods.

conducted immediately to reduce the risk, such as an intensified cleaning procedure. This procedure is above and beyond the routine cleaning and sanitizing. A preventative action is an activity that will prevent future adverse results. We refer to preventative actions as one of the “4Rs,” namely, repair, redesign, replacement, and/or removal. All too often, an adverse event means that the site is cleaned and sanitized, as per the usual procedure, and that is all. On the contrary, this is a call to investigate, immediately reduce risk, and implement one of the 4Rs. Further, all activities are to be documented. We will outline a few of the cGMP programs followed by components that we know are the “secrets” to their success.

## Food Allergen Controls

Currently, there are no cures for those with food allergies or sensitivities. Avoidance is needed to prevent allergic reactions. The FDA recommendations will include that food processing establishments handling any of the major food allergens develop and adopt a food allergen control plan that emphasizes the prevention of cross-contact during processing. Since allergens are part of a food and itself not a contaminate, FDA will be reserving the term “cross-contact” as the unintentional transfer of allergenic proteins from a food containing that protein to food that does not. The terms “contamination” and “cross-contamination” will then be reserved for food that has been adulterated with bacteria, foreign matter, or other-than-allergen proteins.

**Allergen Best Practices.** Verify the cleaning of food contact equipment after allergen use. Do not verify allergens using ATP, which is not a protein, unless the ATP is validated against specific allergen ELISA (enzyme-linked immunosorbent assay) test kits. ATP indicates the presence of adenosine triphosphate or a component of biological material, whereas an allergen is a protein. An ATP assay will not be as specific as an ELISA test and further, it may

(Continued on p. 20)



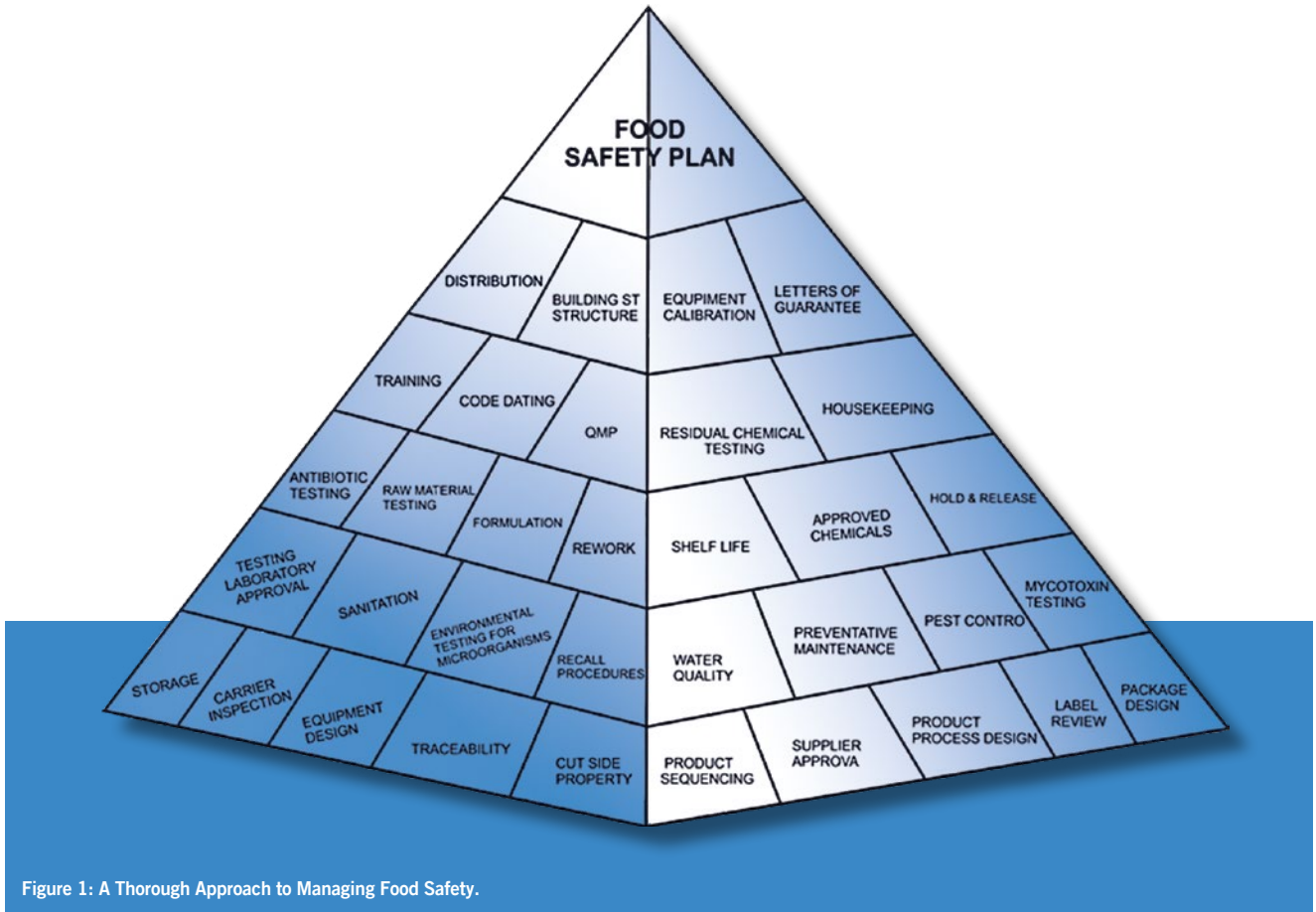


Figure 1: A Thorough Approach to Managing Food Safety.

(Continued from p. 19)

not be as sensitive. ATP assays are cheaper, which is part of their popularity. When testing for allergens, use a test kit that will identify the allergen in question. For example, barley, rye, and wheat cannot be distinguished with some of the commercial gluten methods. However, there are some commercial methods that are not suitable for barley so verification using barley as a control is a critical component of the verification. Similarly, some processing will destroy the test kit's ability to recognize an allergen.



### Personal Hygiene

Driving up to some plants, we have witnessed employees taking breaks outside wearing lab coats and hair nets; walking into production rooms after going on the roof, loading dock, trash compactors; and sitting on picnic tables and leaning on or sitting in their cars with hair nets and ID tags. All of these seemingly innocent activities reduce the effectiveness of a lab coat, hair net, bump helmet, gloves, and shoes. Having an emphasis on protection against cross-contamination of food contact surfaces starts with limiting non-production room exposure.

**Personal Hygiene Best Practices.** Many biological contaminants, such as *Listeria*, are carried in to food manufacturing rooms, either via people or equipment. Outer garments, such as smocks or lab coats, and shoes must be restricted to the more sensitive areas of the plant, such as ready-to-eat (RTE) rooms, and offer

the best protection when they are not removed from production area. An anteroom, located just prior entering the RTE room, or an area immediately inside the production will allow employees to don, doff, store their outer garments and shoes, and wash and sanitize hands and shoes. If there is no space for an anteroom, another alternative is to allow an area for donning and doffing of shoes in exchange with captive footwear. This practice will assist with *Listeria* ingress.

### Plants and Grounds

The facility must employ adequate food safety controls and operating practices or implement an effective design to include separation of operations in which cross-contact and contamination is likely to occur. Separation can be achieved by location, time, partition, air flow, enclosed systems, or other effective means.

**Plants and Grounds Best Practices.** All areas of the facility must be zoned in order to identify the level of risk associated with each. Areas of the facility where there is no further heat-treatment and where the food is exposed is considered to be RTE, High-Hygiene, or High-Risk areas. Other areas of the facility should be designated as Non-RTE, Low-Hygiene or Low-Risk, Raw Area, and General Plant. Each area should have unique procedures that allow (or not) ingress/egress, uniforms, shoe specifications, vehicular/wheeled traffic designations, and employee departmental

(Continued on p. 22)





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determinations. Procedures should be developed for performed activities when unique and risky events such as construction and the removal or introduction of equipment occurs in a high-risk area.

### Sanitary Operations

The proposed cGMPs will require that cleaning and sanitizing of utensils and equipment be conducted in a manner that protects against cross-contact and contamination of food, food contact surfaces, or food-packaging materials, as well as non-food contact surfaces. Additionally, it would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

**Sanitary Operations Best Practices.** A post-sanitation inspection is needed where equipment used for the manufacture of food is visually inspected for cleanliness and then swabbed. Swabbing may be either for ATP (conducted after cleaning) or for indicator microorganisms such as aerobic plate count, coliforms, Enterobacteriaceae (after sanitation), or a combination of both. The sanitation manager should be armed with the ATP swabs as a management tool to quickly assess cleaning and immediately



re-clean when failing tests are returned. Remember to perform a baseline study on the ATP swabs for each plant. Then, immediately after sanitation, the QA team can swab for indicator organisms. Both provide what we described earlier as a verification that the sanitation standard operating procedures are working as intended. Additionally, full equipment disassemblies and inspections (to include swabbing) must be conducted on a routine basis (start with quarterly and readjust as the swabs indicate) for equipment used in support of food manufacturing and starting in the high-risk areas.

### Training

FDA analysis of recalls has indicated that ineffective employee training was a root cause of 24 percent of cGMP-related primary recalls in the 2008 to 2009. As a result, proposed provisions will require that supervisors and workers are appropriately trained and possess the necessary knowledge and expertise in food hygiene, food protection, employee health, and personal hygiene to produce safe food products. Specifically, each person who is engaged in food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) must receive training as appropriate to the person's duties. Training must include:

- The frequency of training,
- The principles of food hygiene and food safety,
- The importance of employee health and personal hygiene, and
- Documentation with the date of the training, the type of training, and the person(s) trained.

**Training Best Practices.** While there is a need for classroom training and presentations, in order to be truly effective, interactive training that is conducted as close to the jobsite as possible is ideal. When evaluating employees for understanding, practical exercises and direct observations is preferred over written tests. Short, frequent training bursts are also a good idea. For example, one plant conducts two four-minute training discussions daily on the plant floor from a list of topics, chosen at random, and documented. Also, while yearly training is important, the really best practice is to provide constant (hour-by-hour/day-by-day) encouragement by on-the-floor management.

Despite FSMA, companies should develop an approach to food safety by combining the efforts of Hazard Analysis and Critical Control Points, preventative controls, and GMPs into one entwined system (see Figure 1 on page 20) where each part works in concert with the others and the entirety is proven effective through scientific verification. So now again we ask will GMPs alone be enough to control the risk of cross-contamination in food manufacturing operations? What do you think? ■

**Dr. Deibel** is the director of microbiology (Food Safety Consulting) for Covance Laboratories, Nutritional Chemistry and Food Safety division. She has worked for over 20 years in the food microbiology field, specializing in food safety controls for pathogens. Reach her at virginia.deibel@covance.com. **Lombardo** is the lead staff scientist (Food Safety and Microbiology) for Covance Laboratories, Nutritional Chemistry and Food Safety division. With over 20 years' experience, he has held many key positions in the food manufacturing industry, including production, quality, and sanitation positions at factory and corporate levels. Reach him at tim.lombardo@covance.com.

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# The Value of GMPs in Achieving Globally Recognized Certification

**An upstate N.Y. juice and sauce processor accounts how it incorporated GMPs in its certification to SQF Level 2** | BY HEATHER ANGUS-LEE

**A**s this year marks the 10th anniversary of the current Good Manufacturing Practices (cGMP) Coalition—formed by 60 food companies and food trade associations working with the FDA to revise guidelines for preventing adulterated foods in production, packing, and holding facilities—it seems a good time to review the role GMPs play today in the industry. As well as serving as the basic principles guiding personnel, equipment, facilities, production, and process controls, GMPs relate directly to Hazard Analysis and Critical Control Point (HACCP) programs, and serve as building blocks for Global Food Safety Initiative (GFSI)-recognized food safety and quality standards. SQF, BRC, FSSC 2200, and other global standard schemes are growing in importance as retail customers demand certification from their food suppliers. GMPs also play an increasingly vital role as the Food Safety Modernization Act (FSMA) emphasizes requirements for a food safety plan that are similar to what is needed for a HACCP plan.

Giovanni Food Company knows all about HACCP plans and globally recognized food safety standard certification. The Syracuse, N.Y.-based company makes and sells salsas, spaghetti sauces, and juices to retailers as well as to the food service industry. Giovanni incorporates GMPs as fundamental prerequisites to their HACCP programs, including the juice HACCP program that is FDA-mandated. In turn, their HACCP programs tie into the SQF Level 2 certification that Giovanni received in 2013.

A couple of years ago, Giovanni underwent a Cook and Thurber audit through NSF International, an audit that “doesn’t have the same recognition within the industry as SQF,” says Alan Patapow, quality manager at Giovanni. “So when it came time to renew our audit, we thought SQF would be more advantageous

*(Continued on p. 24)*

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24 oz. (710 ml)	B01297(WT)WA	B01297(BT)WA	B01297(RT)WA	B01297WA
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to us.” They stayed with NSF for the SQF audits; NSF also oversees Quality Assurance International (QAI), the auditor of Giovanni’s organic certification and soon-to-be gluten-free certification.

“SQF seemed more suitable to us than other GFSI-recognized food safety standards,” says Patapow. “BRC is a lot more involved, and we didn’t feel we needed it all.” A lot of BRC deals with marketing of goods in Europe and while Giovanni Food exports to Israel, Asia, and Canada, they don’t do much business in Europe. Unlike the BRC standard, SQF requires a full-time, onsite standard practitioner employed at the company before, during, and after audits. Patapow is the SQF practitioner at Giovanni; he underwent training at a NSF workshop prior to taking up his role in 2012.

Patapow explains that there are modules within the SQF code that are either general—such as Module 2 that emphasizes food safety through traceability, recall, validation, verification, and management commitment—as well as modules more specific to Giovanni’s business, such as SQF Module 11 that has stipulations around GMPS for personnel hygiene and welfare, building construction, equipment, and pest control. “SQF basically mimics the HACCP program for food safety and risk assessment,” says

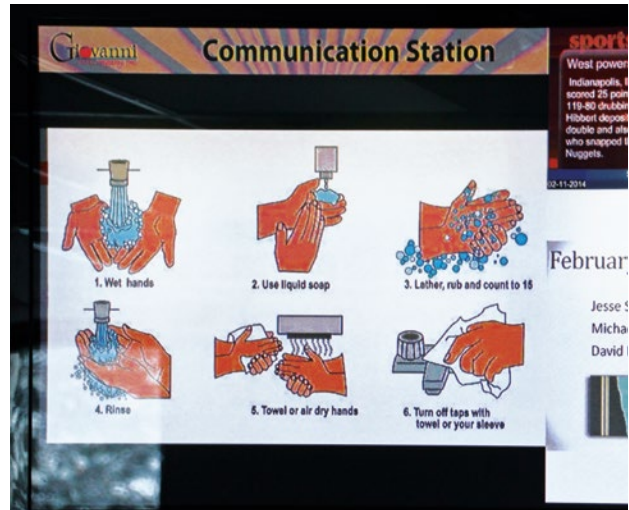
## **GMPs relate directly to HACCP programs, and serve as building blocks for GFSI-recognized food safety and quality standards.**

Patapow, quoting part of SQF Module 2.4.3: “A food safety plan must be prepared in accordance with steps identified with HACCP guidelines’...” He also notes the similarity of that alignment with HACCP with that found in FSMA requirements.

The SQF process “took us a little longer than we anticipated,” says Patapow, who spent about 18 months working on the certification project with a quality assurance assistant. “We had to get practitioner training out of the way, then develop the program. To help us out, we brought in a SQF consultant for several days to conduct a pre-audit. Based on those recommendations, we made the changes needed to our facility and processes, and completed the final audit for Level 2 certification in September 2013.” Giovanni demonstrated their exceptional food safety and quality control practices during the two-day facility audit by NSF.

Process changes were the biggest adjustments for plant workers transitioning into SQF, says Tim Budd, plant manager, Giovanni. “GMPs and food safety were already top priority here,” he notes, but there were changes to the scheduled processes for the products and more formalized monitoring of CCPs for the various HACCP plans. Working with Cornell University Cooperative Extension, processes were established that incorporated these critical factors into HACCP programs to achieve not only food safety, but desired product quality and shelf stability.

Patapow says, “Our QA team would go out and do monitoring training with plant employees, walk the facility and observe these activities, and conduct mock SQF interviews to determine their understanding of some of these changes.”



Giovanni uses a flat-screen TV that constantly features information about HACCP, SQF Level 2, as well as allergen management, handwashing, and other GMPS.

Budd thought TV would be a good way to make sure that critical data is, literally, in the face of his employees “instead of just standing in front of them talking at meetings,” he says. So the company mounted a large, flat-screen TV in the lunchroom on which information constantly scrolls about HACCP, SQF Level 2, as well as allergen management, handwashing, and other GMPS, even photos such as right and wrong label placements on Giovanni products. “The information includes explanations,” says Budd. “If you don’t explain the ‘why,’ it’s meaningless—you don’t get the cooperation from employees.”

Patapow says “the TV approach certainly has bolstered our training and awareness for our food safety and quality programs,” including helping workers prepare for “pertinent information for when the auditor came in.” Indeed, the SQF auditor from NSF told Patapow that she was “quite satisfied by the interviews conducted with employees.”

Giovanni uses ERP software built for the food industry, with functionality that includes automated traceability and recall processes. “Our processes were very manual and time consuming before we started using JustFoodERP. Now it’s easier to show processes for food safety and quality, and we’ve noticed large, rapid increases in the ways we can do the traceability study and mock recall required in our various audits,” says Patapow.

Giovanni also uses quality holds within the ERP system with plans to expand the quality management functionality, says Virginia Shields, production and systems analyst.

SQF Level 2 certification “affords us the opportunity to work with new retailers as we continue to look for ways to grow our business,” says Louis DeMent, CEO, Giovanni. “This certification exemplifies our continued commitment to providing safe, high-quality products to the marketplace.” The company intends, within the next couple of years, to begin working towards SQF Level 3 certification, the highest level that includes more focus on quality, such as quality control points. ■

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# Safety & Sanitation

HYGIENE



## Zoning In on Environmental Sanitation Programs

How to best ensure control of environmental parameters via a thorough preventative maintenance sanitation program

BY CHARLES GIAMBRONE, MS

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In my career, advising food plants on the priority to control the environmental parameters increasingly has become paramount for processors. Environmental Sanitation and EM (Environmental Monitoring) has become a key-stone in a plant's internal EM programs as well as with the Global Food Safety Initiative (GFSI) and federal regulations. In my previous articles "Hygiene Monitoring Strategies that Hit the Mark (April/May 2013) and "Be Ready to Beat *Listeria*" (April/May 2008), while food contact surfaces are a high priority, the environmental niches/zones have increasingly had a profound impact and role on a facility's food safety-sanitation hygiene programs.

There are a multitude of studies that have demonstrated the ability of pathogens like *L. monocytogenes* and *Salmonella spp.* to not only survive but flourish in a multitude of problematic environmental niches inherent in a wide range of food processing plants. While both types of pathogens survive via their vegetative state, not relying on spores for survival, both have their own modes for survival, persistence and biofilm formation.

As is well documented, Listerial species will persist and flourish in moist environments, and will out compete other species in temperatures below 40 degrees Fahrenheit (less than 4 degrees Celsius)

being a bonafide psychrotroph gram positive, soil borne opportunist. While being a gram negative pathogen, *Salmonella* species have exhibited a marked tolerance for dry environs persisting in niches with lower moisture levels than Listerial species require. While not precluding the spore-forming opportunistic pathogens like *B. cereus*, or *C. perfringens*, the other group of microbes that post persistent issues to a plant's environment impacting food quality are the fungal species. Since most result in quality concerns rather than food safety concerns, these opportunistic environmental contaminants can profoundly impact shelf life and form biofilm alliances with a variety of bacterial pathogens. While some environmental niches are similar between vegetative pathogens and spoilage fungi, some are distinct for each group. Below is both a discussion of these environmental niches and their control measures.

### Regulatory, GFSI, Product Type Perspectives

The Food Safety Modernization Act (FSMA) cornerstone is prevention akin to the proactive preventative philosophy of Hazard Analysis and Critical Control Points (HACCP). FSMA has expanded prevention to include HACCP principles to implement preventive controls. One of the key segments is sanitation controls

with mandated verification and validation of the sanitation processes inherent in the operation. Preventive controls include an EM program to verify pathogen control effectiveness which includes not only food contact but environmental zones. In addition, the revision of Good Manufacturing Practices, or GMPs, to incorporate allergen cross-contact controls via preventative procedures is critical and directly involves a facility's environmental sanitation program.

The current focus by FSMA on ready-to-eat (RTE) produce products, the fresh cut, and commodity RTE produce products is that they must rely on sanitation controls both on food contact and environs of a plant or packing house in order to control pathogens and spoilage microbes (to enhance shelf life). The cantaloupe and other produce pathogen outbreaks underscore the need for environmental sanitation as a critical preventative control.

The USDA FSIS 9 CFR Part 430 (2003 onwards) program emphasizes Lm control in RTE meat and poultry products. Alternatives 2 and especially 3 rely on sanitation measures and mandated validation and verification to demonstrate pathogen control of high-risk RTE products.

The GFSI programs, and specifically BRC and SQF, emphasize the mandatory

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development of environmental sanitation and validation programs. Not only do clauses 4.4, 4.7, and 4.10 deal with issues and parameters involving environmental sanitation, namely Building Fabric, Maintenance, and Filters & Sieves, but clause 4.11 on Housekeeping & Hygiene is one of BRC's Fundamental Clauses. 4.11.1 clearly states that "documented cleaning procedures shall be in place and maintained for the building, plant, and all equipment." Also, 4.11.2 focuses on the cleaning and disinfection procedures and frequencies shall be validated. Furthermore, in the BRC appendices, the emphasis of RTE environmental sanitation is very clear in the Guideline on Defining Production Risk Zones by delineation of High Care (Appendix 2.2) and High Risk (Appendix 2.3) in open product areas. "High-care" areas are practices inclusive of environment to minimize pathogen contamination of chilled/frozen RTE products with a high standard. High-care product examples include smoked fish, fresh prepared meals and salads, and uncooked garnishes on RTEs. This is inclusive of both FDA and USDA RTE products. "High-risk" open areas also involve RTE fully cooked products that are susceptible to cross-contamination by *Listerial spp.* High-risk areas are "designed to a high standard of hygiene where practices relating to...environment aim to prevent contamination by pathogenic microorganisms. High-risk product examples consist of fully cooked meats, meals, and dairy products.

SQF deals with environmental sanitation control in a comparable manner. Module 2 under Food Safety Fundamentals (a Mandatory module in both Levels 2 and 3) makes its clear the property, buildings, and equipment shall be constructed, designed, and maintained to facilitate the hygienic production...of safe food. Both for Preprocessing of Plant products (i.e. produce packing houses) in Module 10 and for food processing plants in Module 11, there is focus on the construction and control of product handling and storage areas. Module 11.2 discusses materials of construction and design for all environmental surfaces and has a specific section (11.2.13.1) on Cleaning and Sanitation which includes "The methods and responsibility for the cleaning of the food handling & process-

ing equipment and environment, storage area, staff amenities, and toilet facilities shall be documented and implemented." In addition, Air Quality (11.5.7) pertaining to compressed air hygiene is also emphasized by SQF.

Both BRC (Fundamental Clause 5.2) and SQF (2.8.2) clearly emphasize the high importance of allergen management, which includes proper environmental sanitation procedures and programs to prevent cross-contact onto a processing line. This becomes problematic for dry sanitation processes where wet sanitation methods are limited based on processing line and facility engineering design. SQF, BRC, and other GFSI programs separate high-risk processes (perishable RTEs) versus low-risk processes (raw or baked shelf stable).

### The Environmental Zones

In high-risk operations, both the frequency and level of sanitation procedures, and standards are, of course, far more stringent than in low-risk product processing. However, we can categorize high- or low-risk regardless of product type for this discussion. So let's first focus on Zone 3 items near the food contact zone.

While there is no prescribed frequency for Zone 3 areas, based upon the proximity to the process lines, below are suggested frequencies for your Preventative Maintenance Environmental Sanitation schedule.

#### Zone 3 Daily Sanitation Frequencies:

- Flooring, drains, walls, and covings adjacent to equipment that is floor or table mounted.
- Processing line catch trays or bins that are used to capture soil or scraps viewed as food waste not being reprocessed into product.
- Sanitizer mats/troughs, walk-through boot scrubbers, food transport carts, plastic RTE product pallets.
- Mezzanine or elevated platforms that cross exposed processing equipment/lines.
- Hand sink areas (sink, soap, and towel dispensers) in the production facility.

#### Zone 3 Weekly Sanitation Frequencies:

- Cooler, floorings adjacent to the process modes.
- Overheads, ceilings, covings, walls, and hoses that are in the general area

adjacent to production lines that could create an actual physical, chemical (includes allergens), or microbial cross-contamination of a product on a line.

- Air conveying equipment—includes HVAC units and their condensate pans, air hoses used for processing equipment, or drying of equipment or for packaging equipment. These are verified and validated using both surface swabs for soil and indicators and air sampling for airborne microbes.
- Cleaning equipment, which includes floor scrubbers (tank reservoirs, squeegees, and brushes especially) and condensate pads. Also refuse bins and containers.
- Control panels in close proximity to processing lines or mezzanines.
- Non-food carts.

Zone 4 areas can and do include ceilings, overheads, walls, and flooring that do not directly impact processing equipment or lines. However, the lack of a proper environmental sanitation procedure at the appropriate frequency will definitely cascade microbial and allergen (chemical) contaminants to Zone 3 and the products Zones 1 and 2. Some examples are included below, most of which are either weekly or monthly frequency based on traffic flows/usage.

**Daily Zone 4 Areas:** bathrooms, cafeteria and break rooms, and offices.

**Weekly Zone 4 Areas:** receiving docks, dry storage areas, hallways, and maintenance shops.

**Monthly/Seasonal Zone 4 Areas:** dry packaging storage, intake vents, overheads in nonproduction areas, and loading docks, which can be weekly if shared with receiving or if they are high volume.

A plant/facility's design flaws both regarding product flow and traffic patterns strongly dictates the issues, frequencies, and degree of environmental sanitation required in your environmental sanitation program. The facility's design blemishes or weaknesses will strongly dictate your risk assessment for each and every site in both Zones 3 and 4 in your plant. For example, a well-designed kettle deck mezzanine with accessible surfaces, frames, and overheads will both speed up sanitation efficiencies, and based upon proper design (i.e. 45 degree frame angles versus

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90 degree), decrease sanitation frequencies of environmental Zones 3 and 4. By lowering the risk at each environmental site you also are able to decrease the Verification-Validation frequencies and procedures as well.

Both improper plant design in terms of structural issues inherent in high- to moderate-risk production areas and poor traffic floor design/practices can contribute to high risk for pathogens. For brevity, I'll discuss the aforementioned. *Salmonella* for dry environs and *Listeria* for moist environs. Both can survive either in senescent vegetative or biofilm forms.

*Salmonella* can persist in a senescent vegetative state in relatively dry conditions occurring in a baking or a peanut butter processor. So there are numerous niches where it can survive. This dictates the Zone 3 or Zone 4 EM sanitation frequencies.

Examples include air lines, ducts, aspirators, and dry vacuums. Other areas include eroded or compromised walls, coving, insulation, overheads, conveyors, elevator buckets, fork lifts, and pallet trucks, cat walks, employees, cleaning tools, and maintenance tools. Also insects, rodents, and birds are carriers.

Listerial niches are created and selectively promoted by moisture and refrigerated temperatures. This includes drains, walls, covings, and hoses, gaskets, and O rings, along with unsealed structural tubing or railings. All these compromised areas promote biofilm formation, which a primary survival mode for environmental *Listeria*. Also improperly maintained sanitation items, such as squeegees, footbaths, floor scrubber components, condensation appliances, etc., all can be *Listeria* inoculators.

### What's in Your Toolbox?

In plants where wet cleaning of environmental areas is both permissible and feasible, typical foam cleaners can be employed to clean environmental surfaces.

Obviously when a prescribed wet sanitation



Foaming PAA penetrates sporecoats and provides enhanced residence time of the biocide on target surfaces.

tion is performed on environmental surfaces, the SSOP needs to include a sanitization/disinfection step with a compatible biocide. When the biocide will not be rinsed off, compatibility of the biocides' chemistry must be determined with the surfaces being sanitized. For example, if one has galvanized steel and aluminum structures and you will be applying an acid based quaternary ammonium (QAC) or peroxyacetic acid (PAA), you either have to rinse it off or chose a neutral based QAC to avoid corrosion.

Application of wet biocides, especially for aqueous environmental, is dependent upon the target microbes. If they are sporeformers like *B. cereus* or fungi, a QAC or liquid PAA is not the preferred biocide to eliminate these sporeformers. Rather a foaming version of PAA sanitizer is preferred for all environmental surfaces. Foaming PAA penetrates sporecoats and provides enhanced residence time of the biocide on the target surfaces and attached microbes. As stated above, if one is applying foaming PAA to soft metals on a normal set frequency, after a 30 to 60 minute residence time, the foamed PAA should be rinsed off to avoid corrosion issues.

If you're applying foaming PAA or foaming QAC sanitizers to drains, one can inject foamed sanitizer deep into trough, square, or circular drains including deep into the drain pipes. Also, when one applies QAC above 600 milligram/liter per U.S. EPA label instructions, QAC typically foams. That is why it's utilized quite successfully in wet environments with proper drainage for door foaming units to control *Listeria* cross-contamination.

For those environmental areas that are either inaccessible for wet sanitation or for dry environments, fogging of biocides is a good mea-



For areas that are either inaccessible for wet sanitation or for dry environments, fogging of biocides can help control environmental microbes.

sure to help control environmental microbes. A functional definition of fogging is the aerosolization or particles where over 80 percent are under 20 micrometers in diameter. This creates a dry mist that dries almost instantly. Prior to fogging, dry vacuuming or use of dusting attachments must first be undertaken to remove as much dust and soil as is physically possible prior to fogging. Fogging of any type of

biocides should be done where the room can be confined or is feasible from a cubic meter/footage standpoint. In essence if the room's ceiling height is 20 feet high and the room is the size of a football field, foggers cannot handle the cubic area. Fogging mandates very strict safety protocols insuring personnel are not in the room being fogged, requiring automated timing devices and a time period of 60 minutes to two hours prior to reentry into a fogged room. The application of fogged biocides includes coolers and HVAC units or cooling units in a cooling or freezer spiral. Fogged biocides penetrate deep into a HVAC unit and sanitize those environs in a HVAC system that are inaccessible for wet sanitation. Again, QAC/liquid PAA sanitizers can be effective if vegetative microbes are the primary contaminants, while activated chlorine dioxide is preferred if sporeformers, like fungi or bacilli, are an environmental contaminant issue. If the sanitizer applied in the fogging mode is above the approved food contact level then either all food contact surfaces must be draped with plastic or rinsed thoroughly post fogging. However, sometimes an approved food contact level of a fogged biocide like chlorine dioxide is sufficient, which eliminates the draping or rinsing of contact surfaces. Similar provisions need to be applied in an organic plant which requires sanitizers approved as food contact sanitizers like certified liquid PAA or chlorine dioxide sanitizers available on the market. ■

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REFERENCES FURNISHED UPON REQUEST

# Raising the Standards of Hygienic Design for Processing Equipment

The best cleaning system and most effective sanitizers cannot work properly if the design of the equipment does not follow basic hygienic principles

BY F. TRACY SCHONROCK

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In the more than 40 years that I have inspected processing facilities and evaluated equipment design, I have found an alarming number of equipment buyers and users that equate the mere shininess of stainless steel as hygienic. Stainless steel and other noncorrosive materials are, of course, important but the hygienic aspects of the equipment come from the details of the design. The basics of hygienic design are universal. It does not matter if you are processing dairy products, meat products, fruits, bakery products, or any other of the myriad of food products manufactured, the basics are the same. There may be differences in the details of materials or design features of construction to accommodate a specific product or process, but the overall principles won't change. As the saying goes, "The devil is in the details." And the devil is the potential for contamination and loss of customer trust.

There are a number of false perceptions about hygienic design and hygienic processing, such as the following.

**There are levels of cleanliness.** This is false. Clean is like being pregnant; you either are or you're not. There are, however, levels of soiling that you have to consider as acceptable for your particular process. These may vary from the very slightly soiled, moderately soiled, heavily soiled, to call out the hazmat crew.

**Hygienic design costs more.** In the short run this is often true for some equipment. The materials of construction, often stainless steel, and the design details increase the initial, up-front cost. The long-term benefits of hygienic design over the life of the equipment will reduce the overall operating costs. Often run times can be extended, cleaning times shortened, cleaning chemical and water usage reduced, maintenance costs lowered, and a longer life of the equipment can reduce return on investment. When you purchase less expensive non-hygienically designed equipment, the old adage "You get what you pay for" applies.

**Hygienic design is bad, complicated engineering.** This is false. Hygienic design when applied from the very first steps of the design process is very good engineering. Hygienic features such as the removal of cracks and crevices to eliminate microbiological

contamination also reduce such engineering problems as stress and crevice corrosion. Proper selection of materials of construction can reduce the potential for pitting of surfaces and galvanic interactions between dissimilar materials. Ease of disassembly for

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sanitation purposes is also ease of disassembly for maintenance personnel, reducing downtime.

**We can modify existing designs in-house to be just as hygienic.** In theory this is true. Any design can be retrofitted to eliminate the hygienic hazard issues. It's just a matter of time and money—lots of time and lots of money. The end cost of retrofitting is routinely significantly higher than the purchase of new hygienically designed equipment.

**I don't have anyone on staff that can truly evaluate a new purchase for sanitary design.** You're in luck; the lion's share of this has been done for you and is already available in the market place.

### Standards in Place

The hygienic standards writing organization for dairy and food processing equipment is 3-A Sanitary Standards Inc. Its Standards and Accepted Practices are recognized internationally. During the 1920s, the need for more stringent and uniform standards for dairy processing equipment became evident as the U.S. economy and consumers entered the modern era. Representatives of three interest groups—processors, regulatory sanitarians, and equipment fabricators—saw the need for cooperative action and introduced the first industry standards for equipment. These standards became known as 3-A standards for the three interest groups that forged a common commitment to improving equipment design and sanitation. Unlike other types of standards, 3-A Sanitary Standards relate to the cleanability of dairy equipment.

In 1944, the U.S. Public Health Service offered full cooperation with the 3-A program, which marked the beginning of a program to provide uniform equipment standards for the protection of public health. This integral participation of the regulatory sector of the industry has become important as the food industry complies with the requirements of the Food Safety Modernization Act (FSMA). Under FSMA, the industry must be able to demonstrate and document that they have implemented the necessary steps to assure the wholesomeness of the products they produce and the effectiveness of the cleaning and sanitation programs they employ.

3-A Sanitary Standards' involvement directly benefits the equipment fabricator and the processor through the routine acceptance of the equipment during regulatory inspections.

Today there are 68 3-A Sanitary Standards and nine 3-A Accepted Practices. These documents cover a wide range of the basic equipment used in most food processing applications such as pumps, valves, sensors, heat exchangers, and vessels. There are also standards for specialized equipment for packaging, drying, conveying products, etc. A particular piece of equipment can demonstrate that it has been evaluated by a third-party evaluation and conforms to the hygienic standard requirements with the display of the 3-A symbol.

Over decades of collaboration and recognition among the key stakeholders, the 3-A brand has attained wide recognition in the marketplace for food processing equipment and special stature built on a strong foundation of the following elements: trust, independence, and expertise.

### From the Design Up

Food processors continuously look for the holy grail of increased production, reduced cleaning time, and reduction of costs. These are the areas in which hygienic standards excel. It is desirable to be able to clean the equipment fully assembled or with a minimum of disassembly, and subsequent reassembly; clean-in-place or CIP as it is known in the industry. This is not as simple as just attaching a spray device and a solution return line to the piece of equipment. Even as basic a piece of equipment as a storage vessel with an agitator requires specific engineering to effectively and safely clean fully assembled. Saying that CIP is possible in a sales brochure does not necessarily make it so.

Hygienic design starts with the very first lines drawn on a blueprint. The first task of the designer is to determine what is to be considered a product contact surface in order to assure that the design will fully protect the product from contamination. In hygienic design, a product contact surface is defined as, "All surfaces which are exposed to the product and from which splashed product, liquids, or soil may

drain, drop, diffuse, or be drawn into the product or onto surfaces that come into contact with product surfaces of packaging materials." This definition directs the designer to consider all of those areas of the equipment, which may be over exposed product or open containers in filling machines.

The possibility for successful CIP cleaning has to begin with the basic concept designs as the equipment develops. Every aspect of the design has to be evaluated through the filter of CIP. The concept of the elimination of creaks and crevices must be paramount. Any surface that is exposed to product must also be exposed to the cleaning and sanitizing solutions. Not only exposed, but with sufficient tolerances so that the cleaning solutions can freely circulate to dislodge and flush away product residues. This leads the designer to consider the proper placement of gaskets and seals, the elimination of dead ends where product residues cannot be removed during either processing or cleaning, selection of a cleanable surface texture, selection of materials that will withstand the chemicals and temperatures encountered during processing, cleaning and sanitization, and the inclusion of a proper slope and drainage of the equipment. This list of design considerations increases as the sophistication of the equipment increases. Inclusion of spray cleaning devices opens up design consideration for flow patterns, component placement to eliminate the possibility of shadow areas that will not be properly treated. The attachment of appurtenances, such as valves and sensors and personal access ports, raise more issues that the designer must consider to assure cleanability, as well as the inspectability of the interior product contact surfaces. No matter how efficient a cleaning system is designed, the surfaces have to be inspected periodically. Inspectability and access to the product contact surfaces is a must for assuring continuing cleaning success.

If you want to gain the most efficiency as possible for production and cleaning while increasing your operational cost, equipment boasting hygienic design standards can be a significant benefit. ■

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Simulated organic load with six common food products and dust covering the biological indicators.

## When is it Time to Clean for Facility Decontamination?

A study was conducted to gain a better understanding as to how clean a facility needs to be for a gaseous chlorine dioxide fumigation to be successful

BY PAUL LORCHEIM

In association with sterilizing and disinfecting agents for food processing, the term bioburden is exactly that—a burden. Materials which provide a safe-haven for unwanted microbes by covering and protecting them from decontaminating agents are considered bioburdens. Whether that bioburden is dirt, food remnants, or any other organic load, facilities have always been encumbered by the essential, timely, and overall costly task of its removal. Failure to physically rid focused areas of all bioburden prior to the administration of the decontaminating agent will in all likelihood result in inadequate kill. Due to this constraint, a study was performed to gain a better understanding as to “how clean is clean.” The goal was to determine how clean a facility needs to be for a gaseous chlorine dioxide (CD) fumigation to be successful.

Gaseous CD is an ideal sterilizer. CD is a true gas under ambient pressure and temperature and, when paired with its small molecular size, can be easily distributed into an area to reach inside nooks and crannies smaller than a micron. Its unique molecular composition can be advantageous over those of bleach (hypochlorous

acid), ozone, and hydrogen peroxide by removing 5 electrons opposed to only 2 when reacting with organic loads. Through this process, gaseous CD’s reacting power is sustained for longer periods of time, which in turn, makes it more penetrable.

To understand “how clean is clean,” varieties of bioburdens and an indicator to denote the penetrability of gaseous CD needed to be established. In regard to the former, powdered milk, powdered baby formula, protein powder, flour, sugar, grains, and general dust/dirt were selected to simulate various bioburdens. This selection was based upon food material commonly found in food processing facilities that require physical removal prior to any form of decontamination. Whereas the latter, a Tyvek-wrapped biological indicator (BI), was selected to validate CD’s penetrability through the aforementioned organic loads while still demonstrating a 6-log sporicidal reduction.

### Validation

Unlike antiseptics, germicides, sanitizers, or disinfectants, a sterilizer is the only antimicrobial pesticide that is considered by the U.S.-EPA to eliminate all forms of mi-

crobial life, including spores. Spore forming bacteria is amongst the most difficult bacteria to kill; therefore this is the reason why it is used to validate sterilization. In almost all cases of facility decontamination, validity is gauged by the results of BIs or through the practice of swabbing. The advantage of BIs is that they contain a known amount of organisms and those organisms are in the spore form, which is the most difficult to kill. Generally, a BI used to validate the success of a gaseous decontamination consists of a spore forming bacterium inoculated onto a stainless steel disc or paper strip. Otherwise known as a carrier, the disc or strip is enveloped in either Tyvek or glassine. The population, or amount of individual spores that are inoculated onto the carrier, is critical in determining the logarithmic reduction capabilities of that decontaminating agent.

The logarithmic reduction of microorganisms by a decontaminating agent directly reflects its efficacy. Because BIs have a fixed population of microbes, they are an ideal tool to gauge this effectiveness. In regard to gaseous CD, it is easily capable of yielding a 6-log reduction of all forms of

*(Continued on p. 32)*



**Example 1.**  
Organic loading with protein powder.



**Example 2.**  
Organic loading with various grains.

(Continued from p. 31)

microbial life. To better understand this, a 1-log reduction reduces all microbes by 10 times or 90 percent, whereas a 2-log reduction reduces all microbes by 100 times or 99 percent. Therefore, a 6-log reduction reduces all microbes by 1,000,000 times or eliminates 99.9999 percent of all microbes. Of course the population of organisms associated with the BI must be sufficient enough to support its efficacy. For example, a decontaminating agent cannot demonstrate a 6-log reduction by inactivating a BI with a population of less than 1,000,000 microbes.

For this study, a population of  $1.3 \times 10^6$  *Geobacillus stearothermophilus* spores inoculated onto paper strips wrapped in Tyvek were utilized. Tyvek is comprised of flash spun non-directional polyethylene, which makes it not only durable, but also porous. These microscopic pores are too minute for not only the indicator microbes residing inside the Tyvek to escape, but also for any microbes and particulate outside of the Tyvek to penetrate. Gaseous CD molecules and water vapor however, are easily able to maneuver in and out of these pores.

As a result of this combination, this BI is capable of not only validating a 6-log sporicidal reduction, but can also be used as a tool in determining CD's penetrability through organic loads.

### Gaseous CD Decontamination

For this study, a ClorDiSys Minidox-M gaseous CD generator was utilized to automate the five step decontamination process in an effort to reduce human error.

Earlier studies have confirmed that the following cycle ensures a 6-log reduction of spore forming bacteria. Though these studies were conducted under con-

trolled conditions, they indicate the baseline for which to gauge penetration of gaseous CD through the organic loads used in this study.

Upon loading and executing the standard decontamination cycle on the Minidox-M generator, "Pre-condition" is initiated. During this step, the chamber's relative humidity (RH) is raised by a humidifier inside the chamber. Through continuous monitoring, via an RH/temperature probe, the Minidox-M effectively regulates humidification until the predetermined RH set point is reached. Once satisfied, the generator initiates "Condition," whereby the 65 percent RH residing inside the chamber is maintained and resupplied accordingly for 30 minutes. "Condition" is critical in promoting the susceptibility of bacterial spores to the gaseous CD.

Subsequent to "Condition", the Minidox-M initiates the CD gas injection step referred to as "Charge." CD gas is injected, sampled, and monitored in real-time until it reaches its predetermined concentration of 1 milligram/liter (mg/L). Upon reaching its set point, injection ceases and "Exposure" begins. Just as this step's name implies, all contents located inside the chamber are exposed to the recently injected CD gas. During "Exposure," humidity and CD concentration are continuously monitored in real-time and respectively supplied to the chamber when either falls under their set points. This phase persists until 720 ppm-hrs (parts per million-hours) has accumulated, or 120 minutes of 1 mg/L contact time has lapsed.

### Procedure

Powdered milk, powdered baby formula, protein powder, flour, sugar, grain, and general dust/dirt were selected to simulate organic loads that are commonly

seen in food processing facilities. A set of three *Geobacillus stearothermophilus* populated Tyvek-wrapped BIs consisting of  $1.3 \times 10^6$  spores were assigned to each of these six varieties. Each set was dusted so that the Tyvek side of each BI was covered not only in its entirety, but also generously enough for the identifying text to no longer be visible.

A 17.0 foot<sup>3</sup> polypropylene isolator was utilized as the chamber to conduct this study. The isolator was equipped with various ports and cables for the Minidox-M generator and a carbon scrubber to interface with. Each covered set of three BIs and a single set of three uncovered control BIs were placed inside the isolator along with a small fan, a humidifier, and a probe that monitored both RH and temperature. The RH/temperature probe was connected to an interfacing cable inside the isolator, which was then connected outside to the generator. Similarly, the humidifier was connected to a relay that sat just outside of the isolator, which was then connected to the generator for humidification control. The small fan was plugged into an outlet located inside the isolator and energized to speed up gas distribution. A 0.375-inch CD gas injection tube and a 0.25-inch gas sample tube were then connected on opposite sides of the isolator to avert any false sample readings during the cycle.

The decontamination cycle was started and the Minidox-M successfully raised the chamber's RH to 65 percent, whereby both the chamber and its contents were held at 65 percent RH for 30 minutes. At the completion of this dwell period, the single set of three control BIs were extracted via BI ports on the isolator to avoid any contact with CD. These BIs were immediately incubated in modified



soybean casein digest broth for seven days at 57 degrees Celsius.

Following "Condition," the Minidox-M stepped into "Charge" and injected CD gas until its concentration reached 1.0 mg/L. Upon satisfying its set point, "Exposure" began and the CD gas was held inside the chamber for exactly 720 ppm-hrs. At the completion of "Exposure" the carbon scrubber was energized and any gas inside the chamber was evacuated within a matter of a few minutes. Once concentrations were reduced to 0.0 mg/L, the Minidox-M prompted for cycle completion, at which time the 18 experimental BIs were retrieved. The six sets of three BIs were then immediately incubated, just as the control BIs removed earlier, in modified soybean casein digest broth for seven days at 57 degrees Celsius.

### Results

After the seventh day of incubation, the set of three control BIs resulted in positive growth as expected; indicating that the specific lot of BIs used for this study were viable prior to any testing. Each set

of three BIs covered with powdered milk, powdered baby formula, protein powder, flour, sugar, and grain, of that same lot, indicated no growth. The set of three BIs covered with the general dust/dirt also indicated no growth. This confirms that gaseous CD was able to penetrate all seven of the organic loads and still obtain a 6-log sporicidal reduction.

### Conclusion

Bioburdens such as those tested have a notorious nature of providing refuge and sustenance for unwanted microbes. In a perfect world, any bioburden formed in a facility would be immediately and completely removed. However that is never the case, as it is nearly impossible for facilities to sufficiently clean every crack and crevasse on every wall, ceiling, and floor. As such, there is always some degree of buildup of bioburden somewhere in a facility. This buildup of bioburden creates a more difficult location to clean, as most decontamination methods would be impaired by the existence of bioburden.

Findings from this study did not provide a specific answer regarding how much bioburden needs to be removed prior to administering a decontaminating agent, or "how clean is clean." The results do indicate visually however that gaseous CD is powerful enough to penetrate bioburden to some degree and still achieve a 6-log sporicidal reduction. See photo Examples 1 and 2 for an indication of how soiled a surface can be, with a select choice of bioburden, and still be successfully decontaminated with gaseous CD utilizing the standard cycle dosage. Consequently, the physical removal of significant bioburden remains a necessity while complete removal does not. Thus, even though the impracticality of cleaning every crack, crevasse, and cranny still persists, gaseous CD can be an ideal choice for combating bacteria living amongst overlooked bioburden. ■

**Lorcheim**, the director of operations for ClorDiSys Solutions, Inc., is a licensed professional engineer responsible for directing the commercialization and manufacturing of various decontamination and sterilization equipment for the pharmaceutical, life science, health care, and food industries. Reach him at [paullorcheim@clordisys.com](mailto:paullorcheim@clordisys.com).



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# Testing

INGREDIENTS



## The Daunting Task of Establishing Food Integrity

Along with verifying ingredient identity, the *FCC Identity Standards* include tests for substances that should not be present in certain complex ingredients | BY MARKUS LIPP, PHD

**A**s much as “food integrity” has been part of nearly every discussion related to the food supply chain, the term is in itself unclear to many stakeholders in this arena. On one hand, food integrity implies

a global perspective that includes food production, distribution, and everything in between (procurement, processing, packaging, testing, etc.); on the other hand, it could simply mean the absence of any fraudulent, unknown ingredient in

the food supply chain that would impact food safety and public health.

At U.S. Pharmacopeial Convention (USP), we try to confine food integrity to the food ingredient level, and that means we develop tools to help manufacturers, formulators, regulators, and other parties to assert food ingredient quality (identity, purity, strength, as well as absence of contaminants). The analogy is that our *Food Chemicals Codex (FCC)* can be seen as a dictionary for food trade. The *FCC* is not a specialty dictionary, but it aims to establish a common language and to facilitate communication among the many players in this field. Just as an example, even though a manufacturer of potato chips may have a very nuanced understanding of what “salt” means and how important granularity and crystal flow are from a technological production perspective, his/her understanding of the identity and purity of this ingredient should not differ from how “salt” is described in the *FCC*. The logic seems simple, when applied to describe ingredients such as those consisting of well-defined simple salts or single molecules, but the more complex the chemical composition of a food ingredient, the more difficult it is to determine its integrity.

Food integrity is intrinsic to food safety in the *FCC* context. Being able to determine the safety of food and its ingredients at the basic level depends on the knowledge of its composition. One can only make a safety assessment of those components that are known. Hence, if and when an unknown ingredient is introduced in the food supply chain, it is impossible to establish whether the ingredient and any food produced with it is safe or not, until the presence of such an unknown ingredient becomes transparent. Unfortunately, in some cases this happens only when consumers experience a negative health impact.

### The Challenge

The development and application of identity and purity standards for food ingredients is no easy task. Vitamin A is an example that illustrates what goes into deciding which test methods to use. It is an ingredient used both as a dietary supplement and in food formulations. Often, the term “vitamin A” is used to refer to a

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group of different compounds (including retinol, retinoic acid, and several carotenoids, of which beta-carotene is arguably the best known). All these various compounds have their own features regarding stability, bioavailability, isomerism, and other important parameters. An analyst will have to tailor his/her analytical methods to the specific compound (e.g., provitamin A or beta-carotene to adequately assess its purity and identity). Right there, the definition of what compound exactly is meant by “vitamin A” will trigger a decision about the types of tests necessary to accurately establish authenticity. Questions that feed into the very definition of the somewhat loose term “vitamin A” are: Which are the criteria we want to capture with vitamin A? For which purpose are we testing? The analyst would measure vitamin A by international units if the purpose was related to biological activity and bioavailability rather than a milligram/milliliter concentration, which is how food ingredients are usually measured.

Moisture, or water content, as simple as it sounds, is an important residue to consider and a good example to demonstrate the challenges of setting standards. Moisture is important because it often impacts the chemical stability of an ingredient (e.g. too much water and your ingredient may disintegrate); and, more importantly, it determines the risk of microbiological spoilage. If only very little water is available to microorganisms, this can be measured through determining water activity, which will predict microbiological growth and spoilage. Keeping water activity low is a control mechanism to minimize risks from potentially harmful microorganisms.

But how do you measure water? It seems relatively trivial at first sight (water is water, it is H<sub>2</sub>O, right?), but measuring it in food ingredients may be complex. There are many methods for measuring water, but the way we use them can vary depending if we want to measure water activity or water content. Due to a variety of technical reasons, it is not easy to measure water activity in a reproducible and robust manner and test results depend even on the kind of equipment used.

Water content can be measured by a simple method called loss on drying, which is performed as simply as it sounds. An amount of the given sample is weighed, put in an oven at a certain temperature (typically slightly above the boiling point of water) for several hours, weighed again, and the process is repeated until two subsequent weightings do not indicate further weight loss. The assumption is that all evaporated material is water. This method is not specific because any weight loss is counted as water, even if it is due to flavors, fragrances, and other volatile substances that evaporate. In this specific method, all weight losses are counted as water. The challenge with certain heat-sensitive ingredients, such as milk powder, is that a chemical reaction takes place during the heating process and volatile substances are liberated, of which one is actually water, but not water that has been freely available in the sample, and, therefore, available for microbiological growth. It is water that became available after a chemical reaction took place. These types of heat-sensitive samples may actually continue to lose weight as the process continues and the measurement needs to be terminated after a fixed amount of time that is set by convention (e.g. after two hours in the oven).

Another method is a chemical reaction based on a Karl Fischer titration, which determines all water content that is

present in a sample. While this method is capable of measuring all water in certain ingredients, the method requires complete dissolution of the sample, and that is not always possible to achieve. Besides, just as with the loss on drying method, there is a question of availability of water for microbiological growth, which may not be adequately addressed with this method (e.g. certain salt crystals have crystallization water that is not freely available, but part of the crystal structure, which would not be liberated using the loss on drying method, but it would be liberated and measured as water in the Karl Fischer titration).

So which water do we want to measure?

All these methods are valid and widely used, but they may return different results if applied to the same sample. So, it is important to agree upfront on what is the most scientifically-sound way to measure this one residue. Which method is considered the most appropriate often involves a discussion of regulatory requirements, scientific considerations, ease of use, cost, speed of analysis, and availability of instruments.

### Identity Standards

The examples above illustrate how complex it is to choose even one type of test to help establish food ingredient integrity. When complex ingredients come into play, especially those derived from biological sources, a multicomponent system needs to be considered. A food ingredient monograph many times suffices to establish the integrity of a particular ingredient and the FCC con-

*(Continued on p. 36)*



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tains more than 1,200 of them. However, different approaches may be necessary for ingredients that are closer to raw agricultural products, such as pomegranate juice and other fruit juice concentrates.

Some of the components of pomegranate juice include sugars, polyphenols, acids, minerals, and water that present natural variability that is influenced by the species of pomegranate as well as environmental conditions (region where the fruit is grown, climate, harvest, and processing conditions, etc.).

Recognizing the exhaustive challenge in developing monographs for complex food ingredients, USP last year proposed the creation of *FCC Identity Standards*, which will, more than other *FCC Monographs*, not only establish ingredient identity, but also include tests for substances that should not be present in certain complex ingredients (in the case of pomegranate juice, artificial sugars or compounds that are not usually found in pomegranate, but may be found in other fruit juices with which pomegranate juice has historically been adulterated).

*FCC Identity Standards* are intended as a trigger to perform additional tests to make sure users are not unknowingly purchasing an adulterated product. If an ingredient fails the specifications in an *FCC Identity Standard*, it could as well be due to natural variability of that particular ingredient. However, results that show a particular material is compositionally very different from the majority of the products in that category should raise concerns, or at least questions.

It is important to emphasize that the *FCC* is limited to providing a routine measure to aid in the establishment of food integrity for ingredients that are commercially available. It's not the goal of an *FCC Identity Standard* for pomegranate juice, for example, to represent the composition of pomegranate juice that is obtained from non-commercial processes or sources of the fruits themselves that are not intended for the production of pomegranate juice as a commercial food ingredient.

The intent is to reflect products that are used for commercial formulations, and not all pomegranate juice is commercially available. Part of the challenge for USP is that our standards are not meant to exclude

legitimate products. However, the specifications cannot be so broad that an unreasonable number of illegitimate ingredients suddenly become *FCC*-compliant.

### Risk-Based Assessment

Sometimes, asserting food integrity requires sound judgment paired with appropriate tests and reference materials. Skim milk powder is a widely used complex food ingredient that consists of variable compounds (proteins as a group, which in itself can be divided in numerous fractions, sugars, non-protein nitrogen, fats and lipid-like substances, water, etc.) and could also



## Previous test methods to measure the protein content of skim milk powder have proved not sufficient to keep adulterators at bay.

present natural variability dependent on the species, animal's lactation period, animal's nutrition, as well as processing conditions—heat treatment for instance.

Food analysis is an intrinsic and essential part of helping to ensure the integrity of food ingredients, but it is not sufficient by itself. It is impossible to test an ingredient to safety, and good supply chain management practices are essential components complementing testing. Yet, better tools to help establishing integrity for skim milk powder, for example, and therefore asserting that it is as safe an ingredient as possible is crucial, as instances of adulteration, such as the one in China in 2008, have put public health at risk.

For ingredients such as skim milk powder, USP, in conjunction with industry and academy experts that comprise the Skim Milk Powder Expert Panel, is developing a risk-based testing structure, which is designed to provide guidance to analysts to decide under which conditions more tests might be necessary to gain confidence in the ingredient's integrity and

under which conditions the load of testing may be reduced.

An aspect of risk-based assessment for skim milk powder, for example, takes into account that nitrogen-rich adulterants other than melamine may present a new risk. Previous test methods to measure the protein content of skim milk powder have proved not sufficient to keep adulterators at bay. To help offset the limitations of this test method, USP is coordinating the development of additional tests that are less vulnerable to the presence of adulterants, as well as methods for the non-targeted detection of adulterants and the development of reference materials, or physical samples, adulterated with melamine.

Establishing food integrity should be a task undertaken by all players in an increasingly global food supply chain. Therefore, USP is taking steps to bring together representatives from industry, regulatory agencies, consumer groups, and other standard-setting bodies to discuss proposed *FCC* standards and encourage collaboration.

One of these steps is access to the *FCC* Forum ([www.usp.org/fcc/fccForum.html](http://www.usp.org/fcc/fccForum.html)), where *FCC* monographs and identity standards are open for stakeholder feedback. In-person workshops on selected topics of interest are also available ([www.usp.org/meetings-courses/workshops](http://www.usp.org/meetings-courses/workshops)). In November 2013, USP held a workshop on food and dietary supplements adulteration and in November 2014, USP is scheduled to hold a workshop focused on food contamination. ■

**Dr. Lipp** is the senior director for food ingredients at USP. Reach him at [mxl@usp.org](mailto:mxl@usp.org).

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## Are Your Products Gluten-Free?

Third-party certification can help companies demonstrate compliance with FDA labeling regulations through testing and other quality controls tools | BY JACLYN BOWEN

**G**luten-free products are everywhere: Food retailers carry numerous brands and restaurants have added gluten-free menu items. The once small U.S. gluten-free market is now a \$10.5 billion industry, which is expected to grow to \$15.6 billion by 2016.

But gluten-free products aren't just the latest fad; for the 18 million Americans who suffer from gluten intolerance, gluten sensitivity or celiac disease, they are a necessity. To help assure customer confidence, the FDA issued a final rule last August that defines gluten-free label claims across the food industry. Food manufacturers have until August 5, 2014

to bring their labels into compliance with the new requirements.

The rule requires that foods labeled "gluten-free," "without gluten," "free of gluten," or "no gluten" contain no wheat, rye, barley, or crossbreeds of these grains and no more than 20 parts per million (ppm) gluten. In addition, the rule contains the following details.

- Foods inherently containing no gluten (like raw carrots or grapefruit juice) may use the claim.
- Foods with ingredients of any whole, gluten-containing grain (such as spelt wheat) may not use the claim.
- Foods with ingredients of gluten-containing grains that are refined but still

contain gluten (such as wheat flour) may not use the claim.

- Foods with ingredients of gluten-containing grains that have been refined to remove the gluten (such as wheat starch) may use the claim as long as the food contains less than 20 ppm gluten.
- Foods that contain 20 ppm or more gluten as a result of cross-contact with gluten containing grains may not use the claim.

The final rule applies to all FDA-regulated foods and beverages, including dietary supplements. It does not currently apply to foods regulated by the USDA (such as meats, poultry, and egg products) or the Alcohol and Tobacco Tax and Trade Bureau (such as distilled spirits and malt beverages). Restaurants using gluten-free claims on menu items should also follow the rule.

As of August 5, FDA may use its full range of routine post-market monitoring activities to enforce the final rule, including periodic inspections of food manufacturing facilities, food label reviews,



follow-up on consumer and industry complaints, and gluten analyses of food samples.

If a manufacturer uses a gluten-free claim on its packaging, but fails to meet the requirements of the FDA rule, the product may be deemed misbranded. FDA regulatory action against misbranded products includes monetary penalties, no-sale orders, product seizures, and/or injunctions. It's important for companies at every stage of the supply chain—manufacturers, packers, distributors, and retailers—to have processes in place to assure they are not dealing in misbranded products, including components and packaging.

### What Companies Need to Do Before Deadline

Before the final rule goes into effect on August 5, manufacturers must bring package labels, suppliers, and testing and quality systems into compliance. Retailers and specifiers have the same timeframe to establish purchasing and labeling expectations and disseminate them to their suppliers so the products they carry on store shelves comply with the FDA gluten-free final rule.

**Considerations for Manufacturers and Suppliers.** The FDA gluten-free definition of 20 ppm or less is clear, but the pathway to accomplish this has not been defined. Testing alone is not sufficient to ensure gluten-free compliance. Investing in a quality management system that evaluates supplier assurance, good manufacturing practices (GMPs), and ongoing training is the best option to demonstrate that products reproducibly meet the requirements of the rule.

In order to credibly support gluten-free claims, companies must control for gluten at every step in the supply chain. Suppliers must be able to produce, deliver, and document consistently gluten-free ingredients. This could involve assessments of processes and sub-ingredients, supplier certification, a supplier internal monitoring program, pre-shipment verification testing, and certificates of authenticity.

However, even the best supplier program in the world can be quickly undermined if the manufacturer doesn't follow GMPs and cross-contaminates or comingles gluten-free ingredients with others. Gluten-free products, ingredients, and processes must be segregated. This includes separate ingredient storage, product warehousing, distribution, preparation, and processing as well as personnel, equipment, and smallwares dedicated only to gluten-free processing.

All employees, including supervisors, should receive training that covers ingredients and processing as well as compliance with internal label controls and verification procedures. Employees who handle, formulate, process, and package gluten-free products must receive specific training on awareness and proper procedures.

**Considerations for Retailers and Specifiers.** Like manufacturers and suppliers, retailers and specifiers must also have confidence in their sources of gluten-free products. A structured and well-managed supplier qualification program and approval process is essential. Verification through supplier certification or internal verification testing is a good approach. Separation and hygiene rules also apply in-store, especially for products that are exposed in merchandising.

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### Third-Party Gluten-Free Certification

The final rule does not specifically require manufacturers to test for gluten in their ingredients or finished foods labeled gluten-free. However, manufacturers are responsible for ensuring that any gluten-free claim it makes is truthful and complies with FDA regulations. Quality control tools to accomplish this include conducting in-house gluten testing of ingredients and/or finished foods, employing a third-party laboratory to conduct gluten testing, requesting certificates of gluten analysis from ingredient suppliers, and participating in a third-party gluten-free certification program.

“Third-party gluten-free certification shows that companies have the right processes in place (including a quality management system, good manufacturing practices, supply chain assurance, and employee training) to prevent gluten contamination and to consistently stay below 20 ppm gluten,” says Jim Bail, director of food safety consulting at NSF International.

NSF International has seen a big increase in inquiries from companies about gluten-free certification since the FDA rule was announced. To earn certification under the NSF program, companies must have a gluten-free compliance plan and undergo onsite inspections of their production and handling facilities. Certification also requires ongoing compliance

through annual manufacturing facility inspections and product testing.

NSF analyzes product labels for compliance, examines a company’s processes for shipping, receiving, storing, and handling raw ingredients and finished products, and verifies procedures for sanitation, quality control, testing, record retention, and product recalls.

During the onsite audit, an accredited inspector collects random product samples, verifies the company conducts appropriate raw ingredient testing or sources raw ingredients from a certified gluten-



**Verification through supplier certification or internal verification testing is a good approach.**

free supplier, and confirms that the manufacturer and its suppliers and handlers have procedures to prevent contamination and comingling.

NSF’s gluten-free certification program is ISO/IEC Guide 65 accredited and verifies that products contain 20 ppm or less of gluten in ISO/IEC 17025 accredited labs. NSF microbiologists test food samples using scientifically valid methods for replicable and reliable results. This includes a step-by-step, systemic approach and duplicate methods and controls for test validity.

Scientists use an analytical biochemistry assay with antibodies and a spectrometer to detect and quantify the presence of gluten. Specifically, NSF uses a sandwich-based enzyme-linked immunosorbent assay, or ELISA, kit from R-Biopharm, one of the same methods

the FDA uses. The kit and recommended test procedures, which NSF follows, are performance tested by the AOAC Research Institute.

Global Food Safety Initiative (GFSI) standards (such as SQF and BRC) do not have specific requirements for gluten, but do require training, supply chain assurance, and GMPs. Companies with these procedures in place can combine GFSI and gluten-free audits, and companies already certified to a GFSI standard will likely already meet some of the requirements for gluten-free certification. Likewise, training, supply chain assurance, and GMPs are also core pillars of not only gluten-free compliance, but also of the Food Safety Modernization Act.

### Gluten-Free Labeling Globally

Regulations for gluten-free labeling don’t stop at the U.S. border. Companies looking to export need to be aware of other regions’ requirements. In general, the 20 ppm requirement of the FDA rule is consistent with international standards, including Codex Alimentarius Commission’s revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten, European Commission Regulation No 41/2009 that concerns the composition and labeling of foodstuffs suitable for people intolerant to gluten, and Health Canada’s Food and Drug Regulations.

A difference is that the Codex Standard, European Commission Regulation, Australia New Zealand Food Standards Code, and Health Canada include oats as gluten-containing grains, whereas the U.S. final rule does not.

The Australia and New Zealand Food Standards Code is more stringent and requires foods labeled “gluten free” to have no detectable gluten. The code doesn’t define “detectable,” but current technology can test accurately to 3 ppm.

Some areas allow more than one level of “gluten-free” claim. In Europe, foods containing less than 100 ppm can bear the term “very low gluten” and in Australia and New Zealand, food containing less than 200 ppm of gluten can be labeled “low gluten.” ■

**Bowen** is general manager of NSF International Agriculture and QAI (Quality Assurance International). Reach her at 858-792-3531.

REFERENCES FURNISHED UPON REQUEST

### Gluten-Free Popularity

According to a 2013 gluten-free report from Mintel, the \$10.5-billion gluten-free food and beverage industry has grown 44 percent from 2011 to 2013 as the rate of celiac disease diagnoses and interest in gluten-free foods increase. Some 24 percent of consumers currently eat, or have someone in their household who eats, gluten-free foods. Perceptions of gluten-free foods have moved from being bland, boring substitutes to everyday items that appeal to those with and without a gluten allergy. In fact, three quarters (75 percent) of consumers who do not have celiac disease or sensitivity to gluten eat these foods because they “believe they are healthier.” —FQ&S

# Quality

EDUCATION



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## Cultivating New Credentials in Cyberspace

A growing number of graduate degree programs devoted to food safety and quality are springing up on the Internet

BY LINDA L. LEAKE, MS

**F**lexible. Adaptable. Anytime. Anywhere. That's how Michigan State University (MSU) touts its landmark online Master of Science (MS) in Food Safety graduate program. More than 435 students representing 26 countries, 39 states, and some 227 employers have been accepted into the program since its launch in 2002. "Our average student is a mid-level, mid-career professional working in industry or gov-

ernment regulation," says Julie Funk, DVM, PhD, director of the program. "Professionals come to our online program to advance their food safety knowledge without having to leave their home communities and current employment."

The MSU MS Food Safety program consists of 10 three-credit courses. In lieu of a thesis, a three-credit applied food safety project is part of required 30 credits.

The required courses are Introduction to Food Safety and Professional Development; Evolution and Ecology of Foodborne Pathogens; Food Safety Toxicology; Foodborne Disease Epidemiology; Food Safety Research Methods; Applied Project in Food Safety; and a choice of either International or U.S. Food Laws & Regulations.

The degree can be completed within two to three years, depending on the number of credits taken per semester. "Most students complete the degree within an average of three years, but we do allow a maximum of five years for completion," Dr. Funk says.

Usha Kalro, a nutritionist with the USDA Food and Nutrition Service Supplemental Nutrition Assistance Program, completed the MSU program in 2007 as a compliment to her Registered Dietitian and Licensed Dietitian credentials. "My Master's degree empowers me to speak with authority on food safety topics," Kalro says. "This is a tremendous benefit to my career, my work, and the consumers I serve."

For more information:  
[www.online.foodsafety.msu.edu](http://www.online.foodsafety.msu.edu)

### Virginia Tech

Established in 2006, the Online Master of Agricultural and Life Sciences (ALS) program offered by Virginia Polytechnic Institute and State University (VT) is geared toward adult learners who desire to develop new knowledge and skills in human health and nutrition, sustainable agriculture, food safety and regulation, leadership, and social change, or formal and non-formal education to meet society's changing needs and expectations.

Six degree concentration areas are available for this MS degree including Food Safety; Biosecurity, Bioregulations, and Public Health; Education; Environmental Science; Plant Science and Pest Management; and Leadership Studies.

The VT MS Food Safety option is designed for public health professionals and others interested in the microbiological safety of food, water, and the environment, including the development and enforcement of laws and regulations affecting food production and processing, and the implementation of food safety management programs, according to James

*(Continued on p. 42)*



(Continued from p. 41)

Anderson, II, VT's director of distance and graduate education.

"Thus far, food safety students have represented seven states, but the welcome mat is always out for international enrollments," says Jennifer Carr, graduate program coordinator for the online MS ALS.

Christy Brennan completed the VT MS Food Safety program in 2009. She says her degree was instrumental in helping her transition mid-career from a corporate quality control/food safety auditor position to her current role as rapid response team/manufactured foods specialist with the Virginia Department of Agriculture & Consumer Services in Richmond, Va.

"It is very important for a food industry professional to stay updated on the sweeping changes in food safety," Brennan emphasizes. "Everyone may know their small piece of the puzzle, but it is important to understand how that translates to the big picture of the entire food chain. I believe that continuing education is instrumental in understanding the entirety of today's complex food safety systems that impact public health."

For more information: [www.cals.vt.edu/online](http://www.cals.vt.edu/online)

### University of Arkansas

Established in 2006 at the University of Arkansas, the MS in Agricultural, Food and Life Sciences (MS AFLS) Food Safety is a 30-hour, Web-based, non-thesis MS degree designed specifically for people already in a career track who are interested in an advanced degree in the area of food safety and quality.

"This degree is designed to prepare students for higher positions in the food industry," says Diana Bisbee, EdD, program coordinator. "The program provides a subject matter core of courses in food microbiology, sanitation, food processing, epidemiology, food law, Hazard Analysis and Critical Control Points (HACCP) applications, human diseases, and other quality control areas facing the food industry. In addition, the structure of the courses results in the sharing of food safety knowledge across food companies by addressing complex issues and ever increasing academic rigor."

In a recent survey, students in the program said that if it were not for this program, they would never go back to school

## Onsite Curricula

The following are some on-campus graduate degree programs for food safety and quality offered in North America.

- **Cornell University, Ithaca, N.Y.:** <https://confluence.cornell.edu/display/FOODSAFETY/Cornell+University+Food+Safety+Programs>
- **Illinois Institute of Technology, Chicago, Ill.:** <http://admissions.iit.edu/graduate/programs/school-applied-technology>
- **Kansas State University, Manhattan, Kan.:** <http://foodsci.k-state.edu> (online MS Food Science program also offered)
- **McGill University, Quebec, Ontario, Canada:** [www.mcgill.ca/macdonald/programs/fsqp](http://www.mcgill.ca/macdonald/programs/fsqp)
- **North Dakota State University, Fargo, N.D.:** [www.ag.ndsu.edu/foodsafety](http://www.ag.ndsu.edu/foodsafety) —L.L.



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as traditional students to get an advanced degree, Dr. Bisbee notes.

Students typically take one course per semester (Fall, Spring, Summer) for nine semesters and then work on a special food safety or quality problem. "The special problem is one of the student's choosing and allows the student to set up and conduct an experiment and evaluate the results using the all the skills learned in the MS AFLS Food Safety program," Dr. Bisbee says.

Anyone in the U.S. who meets admissions requirements can enroll. International students who live outside the U.S. are not being admitted at this time.

Suzanne Finstad, director of food safety & regulatory compliance for Tyson Foods, Inc., Springdale, Ark., completed the program in three and half years and graduated in December 2009.

Her employer offers an educational assistance program that provides 75 percent tuition reimbursement in exchange for good grades. "I'm proud to work for a company that fully supports and encourages advanced educational opportunities such as this," Finstad says. "Without the support of Tyson Foods, it's extremely unlikely that I would've found the time to pursue a graduate degree."

Finstad's graduate project was a literature review related to *Salmonella* and broiler processing. Her paper was peer-

viewed and published in *Food Research International*.

Having the ability to develop a project directly related to her work was invaluable, Finstad emphasizes. "Not only was the subject matter of interest to me personally, but it was also of interest to Tyson Foods," she says, calling it "a win-win situation for the graduate student and the company."

For more information: [www.globalcampus.uark.edu/Distance\\_Education/Graduate\\_Degree\\_Programs/MS\\_Food\\_Safety/index.html](http://www.globalcampus.uark.edu/Distance_Education/Graduate_Degree_Programs/MS_Food_Safety/index.html)

### University of Illinois

Since 2010, the University of Illinois (U of I) Department of Food Science and Human Nutrition has offered an online non-thesis MS Food Science degree.

The U of I online MS delivered live and scheduled during the evening, providing students the ability to interact with instructors and classmates in real time and outside of regular business hours.

To earn the degree, students must complete 32 hours of coursework and then successfully pass an oral examination.

Courses offered include Food Chemistry; Applied Statistical Methods; Food Processing Engineering; Food Processing I and II; Package Engineering; Food and Industrial Microbiology; Fermented and Distilled Beverages; Chemistry of Lipids in Foods; and Issues in Food Safety. Ad-

ditionally, Food Science Advanced Topics are available.

Melissa Jones, senior manager of supply optimization at Diageo, Plainfield, Ill., a major premium drinks business, completed her Bachelor of Science degree at the U of I campus in Champaign-Urbana, and then completed the online MS Food Science degree in 2011.

“Both my BS and MS degrees have helped me in product development and everything else I do in my job,” she says. “The MS degree is a great extension of what I learned as an undergraduate and I found the online format to be a great way to earn the degree while working full time.”

For more information:  
<http://fshn.illinois.edu/online>

### Washington State University

The online MS in Agriculture: Food Science and Management (Ag FSM) was launched in 2013 to provide food industry professionals with management skills along with a strong science-based program emphasizing emerging trends in food science, sustainability, and global competitiveness, says Barbara Rasco, BSE, PhD, JD, director of the Ag FSM program.

This recent distance learning degree is affiliated with The School of Food Science, a unique fully integrated department between Washington State University and the University of Idaho.

“Our graduates will be agricultural and business leaders moving freely between labs and boardrooms, between factory floors and corporate offices, and we are all proud to be part of this,” Dr. Rasco boasts.

Professionals in this MS program can select a project emphasis in dairy, microbiological, or chemical food safety, enology, aquatic foods, functional foods, food processing, or law.

The MS Ag FSM is a 30-credit, non-thesis program open to students from around the globe. Like all the other online MS programs showcased in this article, all students pay the same tuition regardless of residency status.

“We are building a virtual community for these students and others in agriculture graduate programs across campus,” Dr. Rasco mentions. “Most of our students are U.S. residents, along with some from

China and South Asia. We will be graduating our first group of students this May.”

Fangliang Carpenter, technical service administrator at Oberto Brands in Seattle, Wash., is one of those MS Ag FSM students who expects to graduate in May 2014.

“The management courses are definitely helping me directly right now in my workplace,” Carpenter says. “My graduate project focuses on writing a review article about jerky and meat snacks, which ties very closely with my current work responsibilities. Empowered with my graduate

degree, I am also enthusiastically looking forward to pursuing a career in food safety and regulation in the near future.”

For more information: <http://msag.wsu.edu/food-science> ■

**Leake**, a 2006 graduate of the MSU online MS Food Safety program, is a food safety consultant, auditor, and award-winning journalist based in Wilmington, N.C. Reach her at [LLLeake@aol.com](mailto:LLLeake@aol.com).

**FOR BONUS CONTENT**, click on this article under the April/May issue at [www.foodquality.com](http://www.foodquality.com).

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# Getting the Most from a Crystallization Process

How scraped surface heat exchanger technology can benefit the crystallization of food products to optimize the quality of new and existing recipes

BY TONY MATHIS



**C**rystallization is important in determining the characteristics and quality of many foods. Good control over this process can establish factors such as whether a particular margarine is spreadable, how oily a product looks and feels and, with the human tongue able to detect crystals down to 55 microns, whether foods, such as ice cream feel gritty or smooth in the mouth. The production and control of these crystallized foods can be revolutionized by scraped surface heat exchanger (SSHE) technology.

## How It Works

As a mixture is cooled in a SSHE the machine continually scrapes tiny, microscopic crystal seeds from the heat transfer wall. Without this scraping action the product would crystallize on the cooling surface and insulate subsequent product

from the heat exchanger, either leading to blockages in the machine or an ineffective process where a thin layer of solidified product prevents cooling and warm product just flows through the heat exchanger. If using a tubular heat exchanger, viscosity increases as the temperature drops and results in less turbulence within the machine. This, in turn, reduces the heat transfer efficiency and requires high-pressure pumping systems for operation. In comparison, the agitation provided by the SSHE maintains turbulence and heat transfer efficiency as the product thickens, ensuring uniform cooling and crystallization throughout the process.

A SSHE provides a constant rate of heat transfer because the film at the product wall is continually being scraped away by its blades. The seeds scraped from the surface of a SSHE get warmed from the stream of product in the machine and,

rather than getting a few seeds growing into large crystals, millions of small crystals are produced. This collection of very fine crystals results in a smooth product with excellent mouth feel.

If larger crystals are required, a portion of the crystallized discharge from the machine can be fed back into the inlet of the SSHE where the cooling process will grow these crystals further. This technique is useful, for example, if forming ice and separating it out in something like freeze concentration. If a product is particularly difficult to solidify, the formation of crystals can be encouraged by adding a certain amount of preformed crystals into the melt at the SSHE inlet. Once the process is running and crystallization achieved as required, the pre-formed solution added to the mix can come directly from the outlet of the SSHE.

## Factoring Temperature

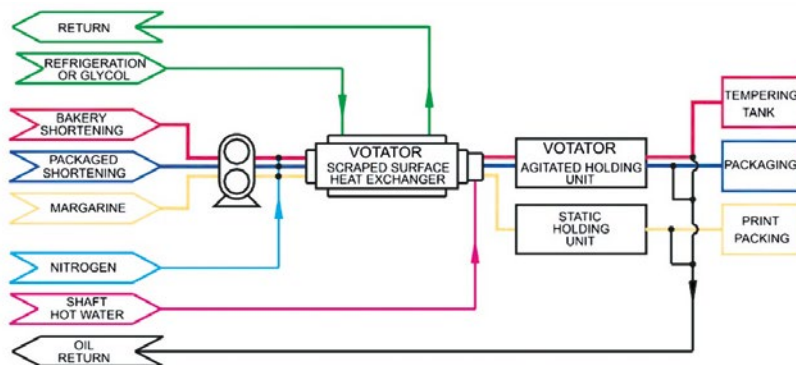
As well as the agitation within the SSHE, which prevents the formation of solid non-plastic product, the cooling rate is also an important factor. Many mixtures contain multiple ingredients which set at different temperatures. If cooling is too slow, these ingredients will set in sequence which can cause separation with liquid weeping from the mixture. Rapid cooling, however, forces all ingredients to crystallize at approximately the same time. Combined with the agitation from the SSHE, this cooling forces the complete mixture to set with small crystal structure.

To enable rapid crystallization for high-capacity production, ammonia, carbon dioxide, or other refrigerants are often used on the jackets of the heat exchangers. Control of the refrigerant side of the SSHE is important for continuous and consistent control of the product discharge temperature and to maximize process capacity. The refrigeration temperature can be adjusted to handle different flow rates for flexible production.

## Healthier Applications

Along with the control of temperature and time for the crystallization process, the constituents of a recipe influence the resulting characteristics of a particular product. In more recent times, aware-





Proces Diagram.

ness of health concerns relating to the use of trans-fatty acids and the amount of saturated fatty acids in food has led to a drive to remove or dramatically reduce these in product recipes. Such changes in requirements have led to enhanced use of palm oil fat and its fractions in recipes, but these oils have slower crystallization speeds than previously used alternatives. To handle this slower rate, the mixture is super-cooled to temperatures below the temperature required to form a solid. Although below the temperature for solidification, the crystals form slowly and the product remains as a liquid for a short time. This gives a choice of secondary processing to achieve the desired structure of the final product.

If the mixture is allowed to stand in static conditions, crystals will continue to grow in a rapid solidification phase and a strong, solid mass will result. If, however, the cooled mixture is moved to a secondary processing unit which agitates the product and adds shear to the mixture, the crystals will be kept small and be prevented from growing together into a solid mass, creating a more fluid result. A pin rotor machine can be used for this purpose and the amount of agitation applied during solidification can be varied to get the right crystal size, texture, and final product characteristics required.

### Fats and Sugars

SSHEs are widely used to crystallize products containing fats or sugars which react differently in the process. Fondants, for example, crystallize very quickly. Bakery sandwich or cookie creams have firm, poor flowing properties and require a machine which can handle the associated high

pressure and high motor shaft torque. The production of low trans- and saturated-fat bakery filling creams, however, also requires care within the process such as distributing gas in the mixture. These creams tend to get too soft if gas is distributed into the mixture at the end of the process with a mixing unit.

Having the right configuration of SSHE means that the gas can be added at the crystallization stage to achieve ideal homogenization while protecting the structure of the crystallized oils and creating the desired consistency of the filling cream for its application. Shortenings and margarines require rapid cooling to avoid separation of the mixture and, as the crystals form, temperature and agitation can influence the resulting product characteristics. SSHEs can be used across all these applications and more but it is important to completely understand all aspects of the process to get the highest product qualities.

A continuous crystallization process in a SSHE not only maximizes production capacity but also minimizes operator intervention and facilitates repeatable, consistent quality results. The quality of the crystallization process largely depends upon the time taken to lower the temperature to the point crystallization occurs, as well as the amount of agitation of the crystals during formation. Faster cooling and more vigorous agitation generally result in the desired smaller crystal sizes within the mixture, giving smooth end product results. ■

**Mathis** is a process technical manager for SPX Flow Technology. His 30-year career has primarily focused on sanitary SSHE heat transfer applications. Reach him at [tony.mathis@spx.com](mailto:tony.mathis@spx.com).

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# Five Ways to Prepare for an Audit

Quick reminders to keep in check when trying to implement an accredited standard | BY SCOTT E. ZIMMERMAN, M.SC, CP-FS



**D**uring an audit, actions often speak louder than words. Audits are largely based on the ability to provide the auditor with evidence that operations are compliant with a standard. From an auditor’s perspective, it is the applicant that controls the outcome of the audit. In general, a lack of organization, untrained staff, and misinterpretation of compliance criteria will put your auditor on alert. Follow these five steps to prepare for your audit, and the auditor will be more comfortable with your implementation of the standard.

**1. Sweat the small stuff.** Not addressing the obvious issues shows a lack of training and overall commitment to the standard. Make sure that conditions throughout the facility, especially storage and office areas, are tidy and things are labeled and in their designated place. There should be sufficient space between the

wall and stored material for pest control and cleaning activities to take place. Your internal audit should be conducted at least two months prior. You might consider having a third party walk through your facility with your audit team to increase the rigor of the audit.

**2. Work as a team.** At least three weeks before the audit, have a staff meeting to prepare. Employees should be familiar with their written job descriptions and the monitoring records they are responsible for. They must understand the hazards related to the CCP identified in the Hazard Analysis and Critical Control Points, or HACCP, plan. Key staff should be familiar with terms such as “corrective action,” and the difference between verification and validation. Management needs to conduct trace exercises at least one week before the audit to make sure team members are comfortable with their roles and

the exercise as a whole. Staff should also be able to explain the difference between recall and traceability.

**3. Do not take a last minute approach to implementing the standard.** Don’t fill out documentation in front of the auditor, or correct deviancies while the audit is being conducted. Don’t use terms like “we try” or “sometimes.” Scheduling your pest management service to come in the day before the audit will not impress an auditor.

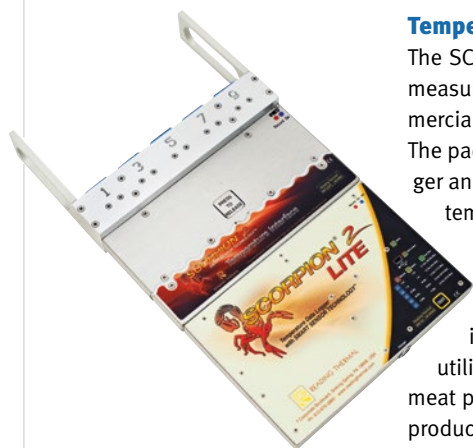
**4. Make sure senior management attends opening and/or closing meeting(s).** I have been on several audits where management is not available to attend either the opening or closing meeting. It is in the best interest of the company for someone in a senior role to be briefed prior to the meeting, and meet with the auditor. Adopting an accredited standard is a serious commitment. Senior management should speak with the auditor about the standard/audit and explain some of the steps that have been taken to comply with the standard.

Senior management should speak with the auditor about the standard/audit and explain some of the steps that have been taken to comply with the standard.

**5. Your best offense is not being defensive.** Do not be offended by the auditor if you have nonconformances during the closing meeting. He/she is just doing his/her job. It’s disrespectful to challenge an auditor if it’s obvious that you don’t comply. An audit is a learning experience for you and the auditor. It’s the auditor’s job to collect data. If you disagree with the findings, take it up through the appeals process. You can challenge the auditor after the report is issued. Stay positive and the audit will go more smoothly. ■

Zimmerman is founder/CEO of Safe Quality Seafood Associates, LLC. His primary focus is GFSI benchmarked certification standards and regulatory requirements for wild and aquacultured seafood. Reach him at info@seafood-certification.com.

# NEW PRODUCTS



## Temperature Profiling

The SCORPION 2 LITE Temperature Profiling Package measures and monitors temperature levels in commercial ovens, cooling tunnels, freezers, and dryers. The package consists of a SCORPION 2 LITE Data Logger and a Temperature Interface that can measure 10 temperatures at user defined positions in a thermal process. Developed primarily for producers in the baked snack food industry, the system has demonstrated potential for application in a range of manufacturing environments that utilize a continuous conveyor process, such as meat processing, nut processing, and aluminum can production. **Reading Thermal, 610-678-5890, [www.readingthermal.com](http://www.readingthermal.com).**

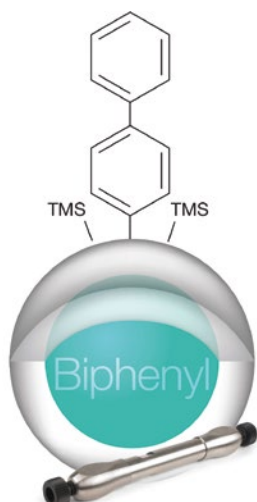


## Sorting Capability

The potato strips Sort-to-Grade feature is now available for all belt-driven G6 optical sorters, including Manta, Optyx, and Tegra. This software-driven intelligence enables sorters to grade by count, accepting or rejecting each defective piece to control the quality of output to a defined grade, as stated by the processor. With Sort-to-Grade capability, accept/reject decisions consider how potentially passing a particular defect, based on its size and color, will affect the overall final product quality in comparison to the processor's specifications. It objectively sorts by count in real-time with 100% inspection. **Key Technology, Inc., 509-529-2161, [www.key.net](http://www.key.net).**

## Biphenyl Columns

Kinetex Core-Shell Biphenyl HPLC/UHPLC columns give researchers the ideal orthogonal selectivity to traditional C18 phases. This new phase is suitable for a range of complex-mixture analyses in clinical research and forensic toxicology and food and environmental testing. Kinetex Biphenyl is initially available in 2.6 $\mu$ m and 5 $\mu$ m with a 1.7 $\mu$ m option expected next. In addition to 100% aqueous stability and enhanced polar basic selectivity, the Kinetex 2.6  $\mu$ m Biphenyl offers versatility for HPLC/UHPLC methods while the Kinetex 5  $\mu$ m Biphenyl offers ideal HPLC performance at low backpressures. **Phenomenex Inc., 310-212-0555, [www.phenomenex.com](http://www.phenomenex.com).**



## Temperature Data Logger

The T&D Food Core Temperature Data Logger features a water- and oil-proof design and complies with HACCP regulations. A clear LCD shows current temperatures, battery level, and more. With one push of a button, the device records temperature, measurement time, item, and makes a judgment result by checking whether the measurement is within the preset upper/lower limits. The data logger can automatically collect and send recorded data to a designated email address or an FTP server over a wireless and LAN network. It can also be used in conjunction with T&D RTR-500 series loggers, which can measure and monitor ambient temperatures in both indoor and outdoor environments. **CAS DataLoggers, Inc., 800-956-4437, [www.dataloggerinc.com](http://www.dataloggerinc.com).**

## Enhanced Beverage Quality Program

The NSF program that provides testing and certification of packaged beverages, bottled water, packaged ice, and flavored beverages to verify compliance with national and global standards has updated its evaluation criteria. These are now more risk-based and support GFSI standards, FSMA requirements, and HACCP. NSF International is offering bundled audits so that when a GFSI audit is undertaken, the product certification requirements can be covered during the same visit. An additional certification focusing on the environmental stewardship of a bottler's source water is also an option. **NSF International, 734-769-8010, [www.nsf.org](http://www.nsf.org).**

*(Continued on p. 48)*



(Continued from p. 47)



### Egg Defoamer

Apex Egg Defoam Plus is a fast-acting, non-silicone, free-rinsing defoamer that can be used in both alkaline and acid cleaning operations. It's clear and colorless, and doesn't leave an objectionable odor. It is highly concentrated and extremely dilutable in water at 1:1000 up to 1:5000. Defoamer is available in 55-gallon drums or 275-gallon totes. **Zep Inc.**, 877-428-9937, [www.zep.com](http://www.zep.com).

### Rheometers

Brookfield adds three new instruments into its touch-screen family of rheometers: the RST-CPS Cone Plate Rheometer, the RST-CC Coaxial Cylinder Rheometer, and the RST-SST Soft Solids Tester Rheometer. They operate in both controlled stress and controlled rate modes and can perform the following tests: viscoelastic modulus, yield stress, viscosity versus shear rate profile, thixotropy calculation, creep behavior, recovery after flow, and temperature sensitivity. Every rheometer offers a wide torque range to handle a range of sample materials. The rugged design allows for use in R&D, working in the QC lab, or on the production floor. **Brookfield Engineering**, 800-628-8139, [www.brookfieldengineering.com](http://www.brookfieldengineering.com).



### Safety Training for Retail Industry

The Food Safety Training Solution provides the retail food sector a comprehensive set of training tools to ensure food safety and maintain regulatory compliance. This is achieved by providing best practices of instructional design and proven adult training methodology. Offered through UL EduNeering business line, key components of UL's training solution can lead to building a robust culture around food safety. Components include preparing participants to sit for one of the ANSI Accredited Food Protection Manager Certification Exams and offering modules specific to sections of the FDA Food Code. **UL (Underwriters Laboratories)**, [www.UL.com](http://www.UL.com).

### Amantadine Detection

The MaxSignal Amantadine ELISA Test Kit detects amantadine residues in meat (chicken, beef, and pork). The test kit, with detection limits of 0.25 ppb in meat, is based on a competitive colorimetric ELISA assay. Amantadine residue present in the sample will compete for HRP-conjugated antibodies against amantadine, preventing the amantadine-HRP from binding to the antibody attached to the well. The resulting color intensity, after addition of the HRP substrate (TMB), has an inverse relationship with the concentration of amantadine residue in the sample. **Bio Scientific**, 888-208-2246, [www.bioscientific.com](http://www.bioscientific.com).



### In Other Product News

**Roka Bioscienc's** Atlas *E. coli* O157:H7 EG2 Detection Assay and Atlas STEC EG2 Combo Detection Assay receive AOAC Performance Tested Methods certification from AOAC-RI.

**Invisible Sentinel's** Veriflow *Listeria* species assay receives AOAC Performance Tested Methods certification.

**Agilent Technologies** and **CambTEK** sign agreement to co-market CambTEK's Rapid Extraction System automated sample preparation technology with an assortment of Agilent's liquid phase separation, life science, and chemical analysis instruments and software.

**Clariant's** Container Dri II desiccant products meet new specifications from the Federation of Cocoa Commerce for protection of cocoa bean shipments in containers.

**Silliker Food Science Center**, a Merieux NutriSciences company, now offers process authority services to support manufacturers of acidified foods.

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## Events

### APRIL

22-23

#### HACCP for On Farm Operations

Salinas, Calif.

Visit [www.scsglobalservices.com/haccp-for-on-farm-operations](http://www.scsglobalservices.com/haccp-for-on-farm-operations).

24-25

#### JIFSAN Annual Spring Symposium: "The Case of Avoiding RISK: Truth or Consequences"

Beltsville, Md.

Visit [tinyurl.com/jifac14registration](http://tinyurl.com/jifac14registration) or call 301-405-8382.

28-29

#### HACCP Training

San Diego, Calif.

Visit [www.scsglobalservices.com/haccp-training](http://www.scsglobalservices.com/haccp-training).

28-1

#### Fundamentals of Food Science Short Course

University Park, Penn.

Visit <http://agsci.psu.edu/fundamentals> or call 877-778-2937.

29-30

#### Dairy Plant Food Safety Workshop

Kansas City, Mo.

Visit <http://bit.ly/J8BylR>.

### MAY

6-7

#### Quality Control Workshop - GMP

Western Dairy Center, Utah State University

Visit [www.usu.edu/westcent](http://www.usu.edu/westcent).

13-14

#### Advanced Sanitation Workshop

Western Dairy Center, Utah State University

Visit [www.usu.edu/westcent](http://www.usu.edu/westcent).

13-14

#### Supplier Food Safety Management

Rosemont, Ill.

Visit <http://sites.usdairy.com/foodsafety/Pages/supplychain.aspx>.

17-20

#### asm2014

Boston, Mass.

Visit <http://gm.asm.org/>.



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# SCIENTIFIC FINDINGS

For access to complete articles mentioned below, go to the “Scientific Findings” section of the April/May issue at [www.foodquality.com](http://www.foodquality.com).



## ARTICLE: Alternative Sanitizing Methods to Ensure Safety and Quality of Fresh-Cut Kiwifruit

In minimally processed vegetables, namely in sliced fruits, chlorine solutions have been widely used by the industry for sanitization purposes. However, reduced microbiological efficiency allied to the sensory alteration and eventual formation of carcinogenic chlorinated compounds pointed out the need for alternative decontamination methodologies. Also, conscious consumers are demanding minimization of the potentially negative impact of food processing on human health and the environment. Therefore, the effect of different sanitizing methods as alternative decontamination treatments to chlorinated-water on microbiological counts, packaging atmosphere composition, color, and firmness of fresh-cut kiwifruit under refrigerated conditions was recently evaluated. The fruits were subjected to water, chlorinated water, ozonated water, UV-C, or heat-shock treatment to determine safety and quality. *Journal of Food Processing and Preservation*, Volume 38, Issue 1, pages 1–10, February 2014.

## ARTICLE: Factors Influencing the Freeze-Thaw Stability of Emulsion-Based Foods

Many of the sauces used in frozen meals are oil-in-water emulsions that consist of fat droplets dispersed within an aqueous medium. This type of emulsion must remain physically and chemically stable throughout processing, freezing, storage, and defrosting conditions. Knowledge of the fundamental physicochemical mechanisms responsible for the stability of emulsion-based sauces is needed to design and produce high-quality sauces with the desired sensory characteristics. This review provides an overview of the current understanding of the influence of freezing and thawing on the stability of oil-in-water emulsions. It focuses on the influence of product composition and homogenization conditions. *Comprehensive Reviews in Food Science and Food Safety*, Volume 13, Issue 2, pages 98–113, March 2014.



## ARTICLE: Optimization of a Process for Shelf-Stable Dietetic Chhana Kheer and Changes in Physicochemical Properties During Storage

Dietetic Chhana kheer has a shelf life of one to two days, even under refrigeration. Problems with such particulate foods have been sought to be avoided by adopting retort processing as there are inherent difficulties in handling such products in a UHT system. Use of retort pouch offers several advantages, such as the ease of handling, reduc-



ing processing time, and faster heating rates. Since retorting has been used to increase the shelf life for several dairy products, research was conducted to develop a process for the preparation of shelf-stable dietetic Chhana kheer in retort pouches with special reference to its sensory and physicochemical properties as influenced by various time and temperature combinations. *International Journal of Dairy Technology*, Volume 67, Issue 1, pages 73–81, February 2014.



## ARTICLE: Crystallization in Lactose Refining—A Review

In the dairy industry, crystallization is an important separation process used in the refining of lactose from whey solutions. In the refining operation, lactose crystals are separated from the whey solution through nucleation, growth, and/or aggregation. The rate of crystallization is determined by the combined effect of crystallizer design, processing parameters, and impurities on the kinetics of the process. This review summarizes studies on lactose crystallization, including the mechanism, theory of crystallization, and the impact of various factors affecting the crystallization kinetics. An overview of the industrial crystallization operation also highlights the problems faced by the lactose manufacturer. *Journal of Food Science*, Volume 79, Issue 3, pages R257–R272, March 2014.



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