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Food Quality & Safety

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Contents

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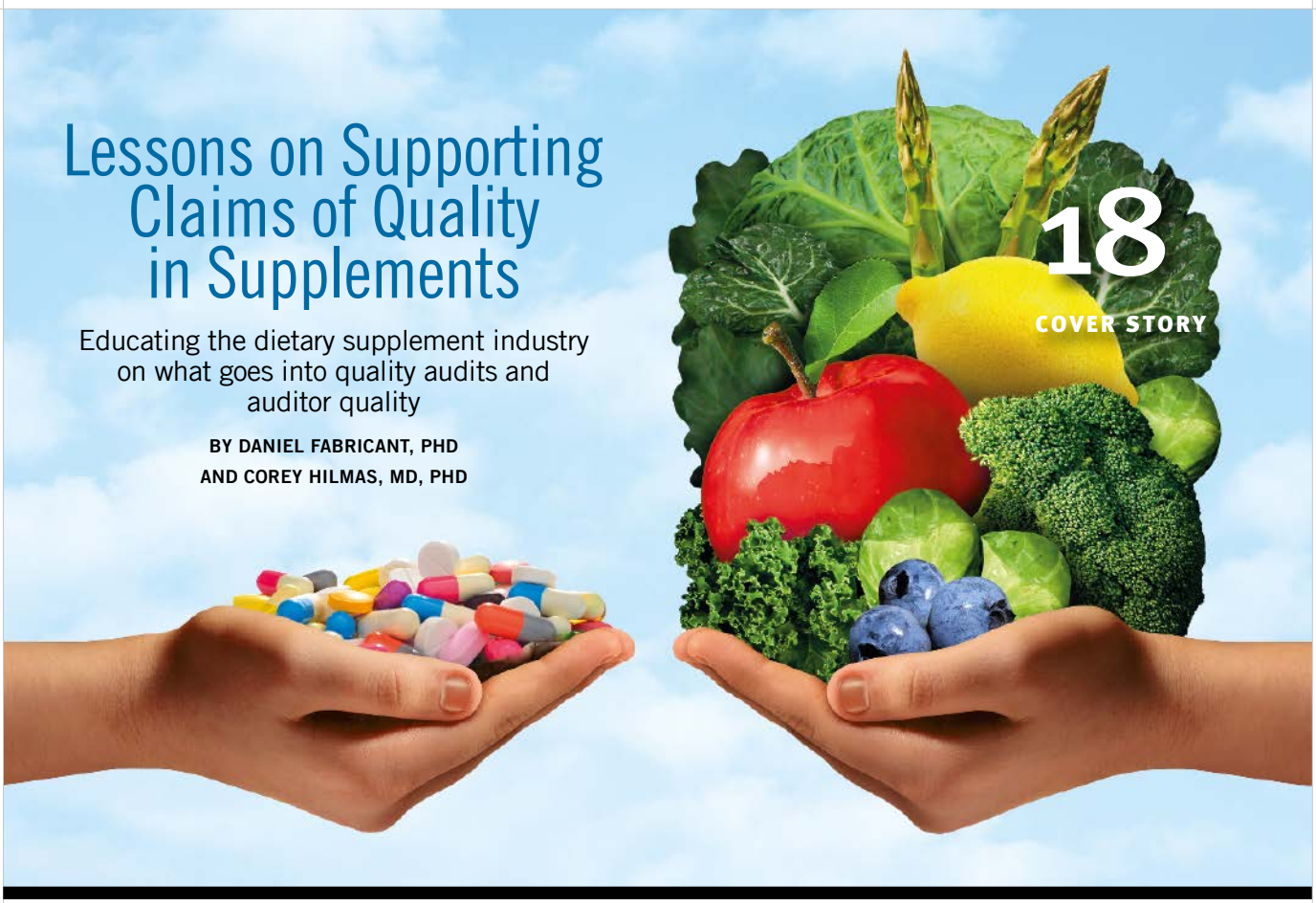

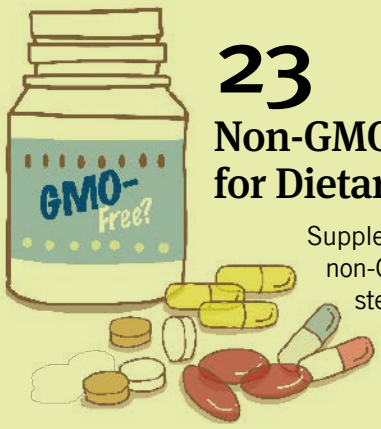

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Features Cont.

Safety & Sanitation

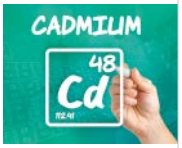
Quality

Testing

Manufacturing & Distribution

Food Service & Retail

Special Report



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Columns

Washington Report

Industry Insights

Around The World

Departments

Exclusive Online Content

To read this article, go to the February/March issue on www.foodqualityandsafety.com:

- The Growing Global Milk Market

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From The Editor

President Barack Obama is looking to consolidate food safety. At press time, the President proposed a bill as part of his 2016 budget plan to create a single food safety agency by combining the responsibilities of the FDA, USDA, and other agencies in order to better protect the food supply.

The proposed agency would be housed within the Department of Health and Human Services (HHS) since food safety and foodborne outbreaks are public health concerns, falling in line with the larger mission of this department. It would be independent from the FDA and be primarily responsible for food inspections, outbreaks, and mitigation.

Currently, most of the responsibility for food safety and inspections lies with the FDA and USDA. However, according to the bill, the current system's "fractured oversight and disparate regulatory approaches" have been known to cause confusion. The bill states that consolidation "is an essential step to reforming the federal food safety system overall."

Agriculture Secretary Tom Vilsack says a single agency would expedite the sharing of information and ensure better coordination, cutting down on delays that could prevent the government from acting—which he acknowledges sometimes occurs due to having multiple agencies. Ultimately, the proposed bill is meant to streamline inspections and eliminate unnecessary overlap.

Of course there are skeptics. One of the main concerns of critics is housing the new agency under HHS. Many worry that food safety won't get the attention it deserves under this massive department because it's already responsible for administrating other important health programs.

Meanwhile, groups like the National Consumers League are praising President Obama's new proposal. "Our current food systems are redundant and fragmented," says Sally Greenberg, executive director. "Consolidating USDA's Food Safety Inspection Service and FDA's food safety oversight will ensure cohesive practices and superior response times in the event of an outbreak, ultimately keeping consumers and our food supply safer."

The group is urging Congress to support the creation of the new food safety agency, but many believe the President's proposal will likely meet opposition in the Republican-controlled Congress...

Marian Zboraj
Editor

Food Quality & Safety
FARM TO FORK SAFETY

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NEWS & NOTES

Assessing Vulnerabilities for Food Fraud

USP releases "Guidance on Food Fraud Mitigation" for the food industry and its regulators to develop and implement preventive management systems in dealing with economically-motivated fraudulent adulteration of food ingredients. The guidance allows individual assessment of all the indicators and factors known to contribute to fraud vulnerabilities and impacts, as well as qualitative tools to make sense of the results. Contributing factors included in the tool go beyond fraud history and include economic and geopolitical anomalies, audit strategies, and supply chain and supplier characteristics.

Environmental Impact Statement

The FDA's Draft Environmental Impact Statement examines the potential environmental effects of its proposed produce safety rule—entitled *Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption*. The draft focuses on four key areas in the rule: definition of covered farms, water quality standards, biological soil amendments of animal origin (such as manure and compost), and actions taken with respect to domesticated and wild animals on farm lands. Only the water quality standards have been recognized as potentially having a significant adverse environmental impact. Draft identifies proposed supplemental changes that would allow time for potentially dangerous microbes in agricultural water to die off, as the environmentally preferred option. The flexibility provided by this option is the reason why most covered farms would not need to change their water source or treat their water with chemicals.

Combating Illegal Fishing

The Presidential Task Force on Combating Illegal, Unreported, and Unregulated (IUU) Fishing and Seafood Fraud releases its recommendations to identify ways for the government to prioritize actions to address IUU fishing and to protect seafood and ecological resources. Some of the key actions recommended include supporting legislation to implement the Port State Measures Agreement setting standards for port inspections to prevent IUU seafood from entering commercial markets; developing best practices for electronic systems to collect catch information, track data, and improve reporting from all vessels involved in the fisheries supply chain, including Automatic Identification Systems and low-cost technologies suitable for smaller vessels; and adjusting tariff codes to enhance identification of illegal species or seafood fraud.

Final Guidance on Labeling of Certain Beers

The U.S. FDA issues final guidance in assisting manufacturers in the labeling of bottled or otherwise packaged beers. Certain beers that do not meet the definition of "malt beverages" are not subject to the labeling provisions of the Federal Alcohol Administration Act. This refers to beers that are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice, or wheat) or are made without hops. These particular beers are subject to the food labeling provisions of FDA laws and regulations.

Listeria Awareness and Education

Focus on Listeria

This year, the International Dairy-Deli-Bakery Association is conducting a year-long food safety initiative campaign called Safe Food *Matters!* to build awareness of safe food practices and serve as an industry resource for food retailers, manufacturers, and their employees. The Initiative will focus on best practices for decreasing the potential for *Listeria monocytogenes* growth and cross-contamination, particularly for deli ready-to-eat foods. Taking the proper steps in educating retail service associates on safe food handling, cleaning and sanitation procedures, equipment maintenance, and good employee practices can help reduce the possibility of *Listeria* growth in perishable service departments.

Business Briefs

NSF International partners with the **American Feed Industry Association** to conduct audits for its Safe Feed/Safe Food Certification Program.

GFSI recognizes **SQF** against the Guidance Document Sixth Edition for the scope of Storage and Distribution.

Mérieux NutriSciences acquires the **Randolph Companies,** which provide technical services to the food industry. The Randolph Companies remain separate entities and will continue to be operated independently of each other.

LECO Corp. broadens its accreditation for Reference Materials under the A2LA Accreditation Program for Reference Material Producers in compliance with ISO.

Washington Report

Food Safety Outlook for 2015

The U.S. food system's New Year resolutions include working within government budgets, meeting inspection goals, and forming better ties with China | BY **TED AGRES**

As 2015 unfolds, federal, state, and local governments will be ramping up their oversight of food growers, producers, and processors in the drive to improve the safety and security of the nation's food supply system. But with financial and other resources lagging or remaining modest at best, this task promises to become more challenging as the global supply chain expands and imports from China and other questionable countries increase.

All this will continue to put pressure on the private sector to take responsibility for food safety. By the latter half of this year, the FDA will publish final regulations to implement five major provisions of the Food Safety and Modernization Act (FSMA). These include final rules for preventive controls for human food and preventive controls for animal food by the end of August, and final rules for produce safety, the Foreign Supplier Verification Program, and third-party accreditation by the end of October. The FDA in September 2014 had issued proposed minor revisions to the first four of these rules, for example, clarifying definitions of small and very small businesses and outlining activities that would re-categorize a traditional farm into a food facility subject to FDA registration and inspection.

Because many of the proposed new changes had been triggered by earlier comments from industry, the final rules are likely to be very similar the second time around. "We don't expect to see much change in the final rules, particularly as the re-proposals filled in some of the expected gaps in the preventive control rules around environmental monitoring, supply chain controls, and product testing," says David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods.

"The big challenge in 2015 will be FDA's obvious lack of resources," Dr. Acheson says. "What will get expensive for FDA is building the FSMA training programs, the education strategies, and the outreach that the agency needs to do with different countries and industries. Unfortunately those resources will be lacking," Dr. Acheson tells *Food Quality & Safety* magazine. "Many small- and medium-sized food companies will be totally clueless about what they need do to comply with FSMA," he adds. But they will have two to three years to comply with the regulations and thus have some breathing room. Big food companies, on the other hand, have only one year to comply after the final rules are published but because most of them have been preparing, they should be well positioned.

Budget Status Quo

The current fiscal year ends Sept. 30, 2015 and thanks to last December's enactment of the Consolidated and Further Continuing Appropriations Act, 2015 (HR 83), the Fiscal Year 2015 budgets for FDA, USDA, CDC, and other food-related federal agencies are locked into place. Under the $1.1-trillion "cromnibus" (for "continuing resolution" and "omnibus") spending bill, FDA's budget rises to $4.44 billion, a $96.7 million (2.2 percent) increase over Fiscal Year 2014. Of this total, about $2.59 billion comes from public funding, which is $37 million (1.5 percent) more than the agency received last year and $4 million more than the White House had requested. The $1.85 billion balance comes from new and existing industry user fees, imposed mostly on manufacturers of prescription and generic drugs, medical devices, and tobacco products.

FDA's Center for Food Safety and Applied Nutrition gets $903 million and the Center for Veterinary Medicine receives $147 million. Food safety activities within these and other FDA centers and offices increase by only $27.5 million over the 2014 funding levels (the White House had originally requested an increase of $263 million, the lion's share of which would have come from user fees). Nevertheless, any increase is vital because the agency estimates it will need $300 million over the next two to three years to fully implement FSMA. Much of this would be used to hire and train more inspectors, improve the agency's aging IT infrastructure, and partner with and provide cooperative assistance to federal, state, and local government agencies to implement many FSMA regulations.

(Continued on p. 12)

(Continued from p. 11)

"I don't believe FDA will have enough resources to pay the states all they need and the states will not have the funding to do it on their own," Dr. Acheson says. For example, state agencies have traditionally been responsible for inspecting farms while USDA's Agricultural Marketing Service (AMS) inspects, certifies, and grades agricultural and other farm products. Under FSMA, FDA will have the authority to inspect certain food safety issues on larger farms, a responsibility it would prefer to delegate. "AMS inspectors are trained in food quality and in grading, not in food safety," Dr. Acheson says. "Someone will have to pay for their training as food safety professionals."

Last year, public health organizations including the Pew Charitable Trusts, the American Public Health Association, and the Association of Public Health Laboratories pressured lawmakers to increase FDA's funding for FSMA. Expect to see similar actions this year especially because of worries that the fiscally-minded, Republican-controlled Congress may be reluctant to grant the agency significant additional funding. Indeed, there already are signs of congressional mistrust; the funding bill gives the inspector general at the Department of Health and Human Services (FDA's parent agency) $1.5 million extra to conduct oversight investigations of the FDA. The bill notes that FDA's resources have increased by more than 60 percent over the past five years as its responsibilities have grown, but effective oversight has not kept pace.

The real reason appears to be more deep-seated. "During the past year, FDA has informed non-governmental stakeholders of important decisions and announcements before they informed the [congressional] committees," according to an explanatory statement of the funding bill, which also carries the weight of law. "A collaborative working relationship between the committees and the agency is necessary to ensure efficient and effective implementation of Congress's funding decisions. These actions jeopardized this relationship. As such, FDA is directed to ensure the committees are notified of major changes to existing policies and any significant developments in its operations prior to providing non-governmental stakeholders such information."

The funding bill gives the CDC nearly $405 million to respond to the growing threats of emerging and zoonotic infectious diseases. Of this amount, nearly $48 million is dedicated to food safety, an increase of $8 million for the agency to acquire "advanced DNA technology to improve and modernize diagnostic capabilities and enhance surveillance, detection, and prevention efforts at the state and local levels." CDC labs receive an additional $7.25 million to "establish cutting-edge lab diagnostics to improve rapid identification and detection of emerging pathogens; establish an innovative e-pathology system to speed communication and establish virtual specimen sharing in real time; and increase research capacity and safety in high-containment labs."

USDA Inspections

The funding bill also allocates slightly more than $1 billion to USDA's Food Safety and Inspection Service (FSIS). In order to counter economic fraud and improve the safety of the nation's seafood supply, FSIS, in conjunction with USDA and FDA, "is encouraged to support developing technologies that will provide rapid, portable, and facile screening of food fish species at port sites and wholesale and retail centers," the explanatory statement says.

As part of its emphasis on prevention of foodborne pathogens, FSIS this year hopes to encourage private facilities to voluntarily develop food defense plans to prevent intentional contamination, with the goal of achieving 90 percent compliance by September 30. FSIS also wants to develop new and enhance existing policies, procedures, notices, and directives to industry to sample, test, and establish new *Salmonella* performance standards for raw ground chicken and parts, raw beef, and raw pork. It will also direct more than 80 percent of its investigative and enforcement activities on food safety issues. In July, FSIS is expected to finalize record-keeping regulations that will require all establishments and retail stores that grind raw beef products intended for commerce to maintain records of their suppliers.

China Food Not Welcomed

The 1,600-plus-page funding bill has been criticized because lawmakers inserted a number of amendments of particular interest to them or their constituents that otherwise would not have been passed into law. One of these provisions bars poultry that is processed and cooked in China from being used in the nation's school lunch and breakfast programs, the Child and Adult Care Food Program, and the Summer Food Service Program. FSIS had previously granted approval to four Chinese poultry processing plants to export cooked chicken to the U.S. so long as the birds had been raised and slaughtered in the U.S., Canada, or Chile. The decision raised red flags, so to speak, among U.S. consumer and other groups because of China's abysmal food safety record.

Democratic Reps. Rosa DeLauro of Connecticut and Chellie Pingree of Maine, both members of the House Appropriations Committee, had added the amendment to the Fiscal 2015 USDA appropriations bill last spring and congressional leaders included the provision in the omnibus spending bill. "Banning Chinese chicken from school meals is a common-sense step to protect our kids," DeLauro said in a statement. "China's food safety record is atrocious, yet last year USDA deemed poultry processed in China to be as safe as poultry processed here. Children are among the most susceptible to foodborne illness. We cannot take unnecessary risks with their health." China, predictably, was not pleased. China's Ministry of Commerce spokesman Sun Jiwen urged the U.S. "to take effective measures to correct the erroneous practice and create a favorable environment for the healthy development of Sino-U.S. economic and trade relations."

Despite this, Washington and Beijing will continue taking steps to improve food relations. Last November, Michael R. Taylor, JD, FDA deputy commissioner for foods and veterinary medicine and point person on FSMA, met with food safety officials in Beijing to discuss improving collaboration. "The legal, regulatory, and technical gaps between our systems are challenging, but we think they can be overcome with sustained effort," Taylor told a food conference in Shanghai at the time. He also announced that FDA hopes to triple the number of full-time staffers in China who focus on food safety—from four to 12. ■

Agres is a freelance writer based in Laurel, Md. Reach him at tedagres@yahoo.com.

Industry Insights

Cracking the Case of a Multi-State *Salmonella* Outbreak

A look at the serious consequences that occurred when a peanut butter company put their profits ahead of safety

BY **DARIN DETWILER, M.A.ED.**

Editor's Note: *This is the first in a three-part account of a 2008-2009 nationwide food safety crisis.*

Bobby Ray "Pete" Hullet, age 67, had recently retired after working for more than 30 years at a glove mill. On a late November Sunday in 2008, Pete began to experience severe dizziness. By day's end, this soft-spoken man was unable to avoid complaining of excruciating abdominal cramps with vomiting and diarrhea. Monday morning, Shirley, Pete's wife of 45 years, and their son Tony, found him on the ground, unable to stand. Tony drove his father to the hospital near their town in North Carolina, where doctors immediately put him on IV fluids, oxygen, and antibiotics. They also collected urine, blood, and stool specimens for the lab to analyze.

As his condition continued to decline, the doctors told his family that every organ in Pete's body was shutting down. On his third day in the hospital—and the day before Thanksgiving—doctors pronounced Pete as deceased.

At about this same time, 72-year-old widow Shirley Mae Almer of Perham, Minn., contracted a urinary tract infection. Her doctor recommended she stay in a short-term care facility near her home. Shirley made the best of it, even enjoying visits from her five children and grandchildren. The staff's treatment of her urinary tract infection was later complicated by stomach cramps and diarrhea.

Although Shirley had the will and the strength to survive her earlier fights with lung cancer and a brain tumor, her immune system was now not strong enough to handle these new infections. The family's plan to bring Shirley home for Christmas was halted as doctors called for the family to gather by her bedside to say goodbye. Shirley's death, four days before Christmas, caught everyone by surprise—even her doctors.

Betty Shelander, age 53, performed as a professional actress/singer/dancer in Los Angeles and New York—even on various television shows—before retiring to North Carolina. On Dec. 27, 2008, Betty began suffering from extreme nausea and vomiting. The next morning, Betty's doctor prescribed some medicine for relief. That afternoon, Betty's husband, Albert, found her unconscious on the floor and called 911.

Betty had no signs of life by the time an ambulance brought her to the emergency room. She was declared as deceased shortly after her arrival. Doctors listed the cause of death as pancreatitis.

On Dec. 23, 2008, health officials informed Tony Hullett that his father's test results came in. Pete Hullett died from *Salmonella Typhimurium*: "Heavy Growth." Several days after burying their mother, Jeff Almer and his siblings learned the cause of her death. Shirley Mae Almer died from *Salmonella Typhimurium*. During Betty Shelander's autopsy, the medical examiner identified the apparent cause of her pancreatitis as a *Salmonella* infection.

The Growing Investigation

In early December 2008, the CDC's PulseNet staff learned of 35 separate cases from 16 states of *Salmonella Typhimurium*—all with an unusual pulsed-field gel electrophoresis (PFGE) pattern.

(Continued on p. 14)

(Continued from p. 13)

Soon, CDC, state, and local investigators had their hands full with a second group of 41 cases from 17 states displaying similar PFGE patterns as the first.

By the beginning of 2009, investigators declared that the clusters shared the same DNA fingerprint and made up a single-strain outbreak. Through the collaboration of CDC and health officials from Minnesota, Connecticut, and Michigan, investigators linked all of the infections to peanut butter.

When CDC officials asked Pete Hullett's wife about the foods he ate, she shared that his favorite treat was Austin-brand peanut butter crackers. "He ate it as a snack two or three times a day—usually just a few before he went to bed."

When Minnesota State health officials asked Shirley Mae Almer's family about what she ate while in the long-term care facility, one of her daughters mentioned that during a family visit she served her mother some toast with peanut butter. According to Shirley's son, Jeff, "She was picky about what she ate, but she liked peanut butter on toast."

An investigation into the foodborne illness that took the life of Betty Shelander tied her *Salmonella* infection to the consumption of a contaminated peanut product.

Traceback to the Unsuspected Source

Minnesota Department of Health determined that the common denominator between the individuals infected was King Nut creamy peanut butter. FDA officials would soon identify the Peanut Corporation of America (PCA) as the only company that produces King Nut brand peanut butter.

Simultaneously, the Connecticut Department of Public Health completed numerous tests on containers of King Nut peanut butter, finding *Salmonella* in each container. The CDC conducted a second study, finding prepackaged peanut butter crackers as another link in the illnesses. Austin and Keebler brand prepackaged peanut butter crackers, produced at a North Carolina facility, obtained their peanut butter paste from PCA.

Federal inspections of PCA's Blakely, Ga., processing plant in 2009 revealed problems that would seem to cause all these illnesses and deaths: dirty conditions in the food processing plant, such as mold and grease–along with bird droppings, rats, and roaches. They also noted leaks in the roof. In addition, inspectors found that the PCA plant did not apply high enough roasting temperatures to kill any *Salmonella* in their product.

Through the collaboration of CDC and health officials from Minnesota, Connecticut, and Michigan, investigators linked all of the infections to peanut butter.

Though the FDA shut down PCA's Georgia plant, Stewart Parnell, PCA's owner, continued operation of his Suffolk, Va., plant. He stated early on that products were not shipped back and forth between PCA's various facilities in different states. This statement proved to be false.

Unbeknownst to investigators, PCA also had a peanut processing plant in Plainview, Texas, where Kenneth Kendrick served as assistant plant manager for several months in 2006. Back then, Kendrick observed numerous problems in the Texas plant, including rat infestations, bird nests, and a roof leak—all of which triggered his concern for feces in the product. According to Kendrick, "particularly with water leaking off a roof, bird feces can wash in and drip onto the peanuts."

Kendrick sent anonymous emails and letters to the Texas Department of Health and to companies that purchased products from his plant—but he never received a response.

In 2006, after only a few months on the job, Kendrick chose to leave his position with PCA because as he stated, "I knew it was a train wreck and something unethical and bad was about to happen."

When Kendrick learned that the widespread *Salmonella* outbreak in 2008-2009 traced back to PCA's Georgia plant, he spent "hundreds of hours" trying to contact the media and federal food or health agencies to get attention placed on the Texas plant as well. The only response he received was from the Chicago office of STOP Foodborne Illness, a non-profit food safety organization. STOP convinced FDA officials to meet with him in January 2009. The organization also connected Kendrick with a reporter at *The New York Times* and a producer from ABC's *Good Morning America* show.

Texas officials had no idea that the Plainview facility even existed. Parnell had not registered his Texas peanut facility as a food processing plant with the state. As a result of Kendrick's whistleblowing, federal authorities and the Texas Department of Health investigated the Texas plant as another source of the outbreak. His information helped prove that peanut products were being shipped between PCA facilities in different states–contrary to what Parnell had told the public and investigators throughout the outbreak.

On Jan. 28, 2009, Texas authorities ordered PCA to stop distribution and recall their product out of the Texas facility. At the time, its peanuts were ingredients in more than 3,500 products produced by numerous companies, such as King Nut and Austin.

Federal authorities identified PCA as the cause of the multi-state *Salmonella* outbreak that sickened 714 consumers in 46 states and caused the deaths of nine people between September 2008 and March 2009.

Victims' families, including those of Pete Hullet, Shirley Mae Almer, and Betty Shelander, would wait almost six years to see Parnell and other executives from PCA brought to justice. Though the U.S. Department of Justice indicted four executives from PCA in February 2013 on 76 criminal charges including the sale and distribution of adulterated food, none of the charges would technically involve PCA's sickening or killing of their consumers. ■

Detwiler is the senior policy coordinator for food safety at STOP Foodborne Illness. He has over 20 years of involvement in food safety reform, including having served two terms as a USDA regulatory policy advisor on meat and poultry inspection. Detwiler teaches the Regulatory Affairs of Food at Northeastern University where his is also a Doctoral Candidate in Law and Policy. Reach him at ddetwiler@stopfoodborneillness.org. Contributing to this article were **Wendy Maduff**, PhD, a food scientist, and **Pamela Crawford**, a food industry student of the author.

COMING IN APRIL/MAY ISSUE... The next article in this review will focus on the PCA scandal from a whistleblower's point of view.

Around The World

Out of Africa

Food safety and quality initiatives are growing on this wildly diverse continent | BY **LINDA L. LEAKE, MS**

Editor's Note: *This is the second in a six-part series of articles that will showcase food quality, safety, and regulatory issues of each continent.*

"If you give bad food to your stomach, it drums for you to dance." So goes the African proverb associated with food safety. While it could be said that all 1.1 billion Africans share the implications of this adage, Africa is definitely a continent of contrasts, says Lucia Anelich, PhD, principal of Anelich Consulting, Pretoria, South Africa.

"We have a number of countries relying on subsistence farming and predominantly street food vending to feed their populations," Dr. Anelich begins. "Other African countries are more developed in varying degrees. Only a few have formalized agriculture, with first world commercial farms and associated support industries such as fertilizer, seed, and crop management companies, and also well-developed manufacturing and retail sectors offering the consumer a wide variety of food products."

According to Dr. Anelich, South Africa is the most developed country on the African continent, boasting a solid infrastructure, and a well-established formal food production, food processing and manufacturing, and food retail system, with supporting regulations she characterizes as the continent's most advanced legislation in terms of food safety.

"South Africa has a well-established farming, food manufacturing, and retail sector that caters to the domestic, regional, and international markets," she elaborates. There are multinational companies that operate food production plants in many African countries, but South Africa remains the most developed in this regard."

The continent of Africa consists of 54 very diverse countries. Covering 11.7 million square miles, the landmass of the world's second-largest and second-most-populous continent is larger than the U.S., China, Japan, India, and Europe combined. Offering hope for greater cooperation and peace among the continent's countries, the African Union (AU), a 54 member federation consisting of all of Africa's states except Morocco was formed on June 26, 2001, with Addis Ababa, Ethiopia as its headquarters.

Growing Economies

African economies are growing, and thus food economy and international trade in food is becoming an integral part of that economic growth, Dr. Anelich says.

To that end, cocoa, coffee, cassavas, yams, mangos, and bananas, which are normally raw produce, are some key export commodities from a number of African countries, according to Courage Kosi Setsoafia Saba, PhD, a lecturer in food microbiology and food safety with the University for Development Studies (UDS) in Tamale, Ghana.

"Countries in Africa are becoming more involved in regional and interna-

(Continued on p. 16)

(Continued from p. 15)

tional trade in order to generate foreign currency," Dr. Anelich relates. "To that end, a certain level of food safety must be achieved before food trade can occur. Moreover, when countries can supply safe and nutritious food for their domestic markets, they are better able to ensure adequate health and growth of their respective populations so citizens can then contribute in a meaningful way to long-term economic growth of that country."

All countries in Africa have food standards, Dr. Anelich points out, but they range from very few and rudimentary standards to antiquated standards developed during colonial times to more modern standards reflecting the spirit of the World Trade Organization (WTO) and the Codex Alimentarius Commission (CAC).

Consequently, projects exist within Regional Economic Communities to harmonize existing food standards, Dr. Anelich relates. "However, many existing food standards are not based on scientific principles as per the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and the Technical Barriers to Trade Agreements (SPS and TBT)," she says. "Rather, these may be either too lenient, allowing for easier importation of unsafe foods into those countries, which may pose a risk to human health, or the standards may be stricter than Codex standards, which may then constitute a barrier to trade (as per the WTO Agreements) if the stricter standards are not scientifically justifiable. Because of all this, it is clear that further development of science-based food standards is required."

For this to occur, Dr. Anelich says, capacity building is required in those African countries that do not possess scientific expertise relative to conducting risk assessments and incorporating the results of those risk assessments into appropriate food standards.

Easier said than done. Capacity building requires political will as a first step, followed by policy development and long-term strategies for maintaining that capacity in a particular country.

"This is vital to enable effective participation in relevant regional and international forums such as the Regional Economic Communities and the CAC, respectively," Dr. Anelich emphasizes. "These developments should, however, go hand in hand with harmonization of food standards at regional and international levels, in order to facilitate trade."

Most countries in Africa are members of the CAC and WTO. "It therefore follows that Codex Alimentarius standards are the minimum standards that these countries should comply with," Dr. Anelich continues, "not only for conducting international and regional trade, but also for providing safe and nutritious domestic food. To that end, Africa is in this development trajectory."

COURAGE KOSI SETSOAFIA SABA

Street vendered cow skin, locally called "wele," in tomato sauce for sale in Ghana.

As part of its capacity building program, the AU has set up a number of expert committees that "mirror" certain Codex committees. "These consist of experts within that field that meet once per annum in Nairobi at the AU-Inter-African Bureau for Animal Resources offices and develop a response document to the items on the Codex committee agenda," Dr. Anelich relates. "This document becomes a common African position that is then sent to all the National Codex Contact Points in Africa for those countries to use as a response to that Codex committee. This is certainly bearing fruits, as we are seeing more meaningful participation from African countries in Codex meetings."

Dr. Anelich, a microbiologist, serves on the AU's Food Hygiene Expert Committee. Other expert committees include Food Contaminants; Food Additives; Food Labeling; Pesticide Residues; Nutrition and Food for Special Dietary Uses; Residues of Veterinary Drugs in Food, Fish and Fisheries Products; and Fresh Fruits and Vegetables. New proposals for expert committees are Food Import and Export Inspection and Certification Systems; and Methods of Analysis and Sampling.

In addition, says Dr. Anelich, large countries and blocks such as the U.S. and the European Union (EU) are now wishing to have discussions with African delegates the day prior to the Codex meetings to discuss various matters on the agenda. "This level of interest in African positions was not apparent before this program started a few years ago," she notes.

The AU is currently spearheading an African food safety authority. In early stages of development, the initiative is projected to set safety standards for and monitor the African food supply, much like the European Food Safety Authority does for EU member states. In October 2014, organizers met to investigate developing a Rapid Alert System with the following objectives: 1) Quick exchange of information about food and feed-related risks to ensure coherent and simultaneous actions by all network members with the view of protecting consumer health from eminent public health risk, and 2) Contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for trade in food.

What About HACCP?

"Hazard Analysis and Critical Control Points (HACCP) programs are implemented in many countries, particularly amongst multi-national companies operating in African countries," Dr. Anelich says. "However this is not necessarily the case with small domestic businesses and even larger, less-developed domestic businesses. HACCP-based systems are implemented widely in South Africa and South Africa has the most companies certified to HACCP-based systems by third party audits from accredited certification bodies than any other country in Africa."

"HACCP programs are implemented occasionally in the larger manufacturing companies in Ghana, especially if there are problems with their products, but the small-scale producers don't implement HACCP," Dr. Saba says. "Companies are monitored by the food regulatory bodies in the country but the enforcement is actually very weak, coupled with inadequate expertise. Food safety auditing is virtually none existent here."

COURAGE KOSI SETSOAFIA SABA

Street vendered fried chicken and guinea fowls sold in an open stall in Ghana.

Dr. Saba emphasizes that he speaks only for his own country, but he says that Ghana's situation in food safety is likely the norm in many other African countries.

For example, implementation and enforcement of food regulations is a big challenge in many African countries, Ghana included, says Dr. Saba. "The major food safety issues in Africa are foodborne illnesses and inadequate food hygiene practices," he stresses. "Compounding this, some people don't believe illnesses are caused by unwholesome food."

There are an estimated 2,000 food safety-related deaths in Africa each day, according to the United Nations Food and Agriculture Organization and the World Health Organization. An estimated 700,000 deaths occur in Africa each year due to diarrhea associated with contaminated food and water, according to Dr. Anelich. Reported foodborne disease outbreaks in Africa show that the majority are caused by *Salmonella spp*., *Shigella flexneri*, *Shigella sonnei*, and *Shigella dysenteriae*; plus *Bacillus cereus*, *Staphylococcus aureus*, and *Clostridium perfringens*. Various types of parasites are also a significant cause of foodborne illnesses in Africa.

"The presence of illegal levels of food additives such as E110, E102, E104, and E124 in local and imported products, especially in children's foods and drinks, without any indication about their possible adverse effects written on labels, is a problem in Africa, and there is virtually no equipment here to test food for recommended levels of additives," Dr. Saba says.

"Inadequate testing laboratories is another quagmire to food regulation in Africa that makes it difficult for regulators to take swift action when problems occur," he continues. "Many labs have inadequate testing equipment and expertise. As a result it can take months or years for some analyses to be done, and some samples have to be sent out of the countries for analysis. Our local food and drugs authority (FDA) doesn't have adequate capacity and has to send their samples to Accra, Ghana's capital city, which is about 373 miles away, and Accra only has one lab serving the country's FDA."

Currently managing the UDS faculty laboratory complex, Dr. Saba helps the FDA in his geographic region to test certain locally produced products that are striving to meet the Ghana FDA standards for the certification of products. This testing includes proximate analysis and microbial analyses of locally produced beverages like sobolo, which is made from dried sorrel flowers flavored with sugar and ginger, and also milled cereal/legume products, including Tom Brown (roasted-maize porridge), a traditional weaning food and dawadawa (a.k.a. sumbala), a condiment made from néré (*Parkia biglobosa*) seeds or soybeans that is traditionally sold in balls or patties.

Other weaknesses in food safety and quality initiatives in Africa include low literacy rates, governments not prioritizing food safety, and inadequate funding for continental food safety organizations, Dr. Saba mentions.

Looking Forward

Dr. Saba says the African populace is becoming more aware of food safety issues than ever before. "This makes it easier for most consumers here to take on manufacturing companies for their actions or inactions," he purports.

Aside from the many challenges that face Africa, there are also a number of opportunities, Dr. Anelich emphasizes. "Africa is clearly on a growth trajectory, with an average growth rate of five percent per annum, which it has maintained over the past few years, with some countries showing a higher growth than five percent," she says. "There are definitely opportunities being grasped to exploit the agricultural and food producing potential of Africa. Thus, there is no better time than the present to ensure that food standards are developed and/or revised in keeping with WTO, SPS, and TBT Agreement principles. This approach will facilitate harmonization of food standards, and consequently food safety standards, at regional and international levels." ■

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For bonus content on food safety in Africa, go to February/March 2015 issue on www.foodqualityandsafety.com and click on "Out of Africa."

Lessons on Supporting Claims of Quality in Supplements

Educating the dietary supplement industry on what goes into quality audits and auditor quality

BY **DANIEL FABRICANT, PHD** AND **COREY HILMAS, MD, PHD**

MONTAGE: FQU / FOTOLIA.COM(3)

Wherever you travel around this country—and even internationally—you will likely hear the same rhetoric from dietary supplement manufacturers. Firms claim they have quality, something that their competitors do not, and they are doing it the right way despite not allowing an external audit for quality and compliance by a third party. When one of us hears this from a company, we typically respond by asking how they know this to be true, and we are left feeling surprised that more dietary supplement firms do not use a quality audit from a third-party certification organization to demonstrate the adequacy of their quality systems, considering its benefits to benchmark continuous process improvement and relatively low cost.

When you look up the word quality, you will find that it is an attribute or defining characteristic that has become the standard as measured against other things of a similar kind. In a world where we group according to the buckets of good, better, and best, quality is the degree or extent along the scale to that asymptote we call perfection, an impossible point we can never reach. Many may not be familiar with the teaching of W. Edwards Deming and his 14 points for continuous process improvement, but they are quality concepts that have passed the test of time. Deming was a U.S. statistician of mathematical physics, and a pioneer of modern quality management. He developed the founding principles of Total Quality Management and the System of Profound Knowledge. Deming introduced the DMAIC and PDC(S)A acronyms, which have been

quoted in every quality seminar since the 1980s. DMAIC stands for Define Measure Analyze Implement and Control and PDC(S)A stands for Plan Do Check (Study) and Act. These acronyms and Deming's 14 points of quality management gave birth to Six Sigma by Bill Smith of Motorola, many of the concepts of ISO9000 series and the ANSI Q90 series standards issued today for quality improvement, and Lean training of the '90s.

Keeping Up to Standard

Intrinsic to demonstrating quality for any firm is implementation of an external quality audit and certification to an industry standard. Given the choice available to the industry, there is no shortage of auditors for part 111 current Good Manufacturing Practices (cGMPs), but there is quality and, therefore, value in the services of an audit. The results of a third-party quality audit provide a benchmark assessment of the adequacy of the existing program as it sits statically in the present, and an assessment of weaknesses to drive continuous process improvement into the future.

The Natural Products Association (NPA), formerly the National Nutritional Foods Association, created the first GMP standard for performing quality audits as well as certification in the dietary supplement industry. NPA is committed not only to advocating for the rights of manufacturers, suppliers, and retailers to have a marketplace in which to sell products but also to consumers having access to quality products in order to maintain their health

(Continued on p. 20)

Associations will typically develop self-regulatory programs or initiatives which demonstrate industry transparency and maturity, and provide the consumer valuable information that can be used to evaluate products.

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and well-being. NPA has developed a long and diverse array of self-regulatory initiatives and programs, all of which were firsts for the natural products and dietary supplement industry.

To advocate both consumer and industry concerns, associations will typically develop self-regulatory programs or initiatives which demonstrate industry transparency and maturity, and provide the consumer valuable information that can be used to evaluate products. The public and private benefits of industry self-regulation are numerous, and they typically outweigh the costs incurred to industry. First, self-regulatory programs and initiatives may lead to the establishment of product or ingredient standards to ensure quality and safety. In turn, these standards may facilitate the emergence of markets by establishing baseline levels of product quality and safety; result in improved consumers' understanding; impart brand recognition through seals/marks representing third-party certification; induce brand loyalty; and garner trust of new products.

Standard setting and implementation can be a further benefit to manufacturers by lowering production costs, which can be

Microbiology Testing by Dietary Supplement and Nutraceutical Companies

BY **TOM WESCHLER**

In June 2010, the FDA's Final Rule on Dietary Supplement cGMPs became effective and all companies that manufacture, package, label, or hold dietary supplements and nutraceuticals, as well as products imported into the U.S., were expected to be in compliance. cGMPs require a comprehensive system of process controls, and document each stage of the manufacturing process, in order to minimize and detect problems early if they arise.

It's difficult to know the types and extent of product quality and safety testing by dietary supplement and nutraceutical (DS/N) companies prior to the FDA's Final Rule. In interviews conducted for Strategic Consulting, Inc.'s (SCI) latest report, "Industrial Microbiology Market Review" (IMMR-4), however, many companies reported needing to move quickly to comply with the microbiological testing required by the FDA Final Rule. The regulations required DS/N companies to demonstrate that the microbiological levels in products are below target levels and that no "objectionable organisms" are present in view of the product's intended use.

According to IMMR-4, DS/N companies conducted approximately 35 million microbiology tests in 2014. While this represents significant change for these companies, it accounts for just two percent of the micro testing conducted in the entire industrial market, which covers the food, beverage, personal care products/cosmetics, environmental water, and industrial processes sectors.

A good number of DS/N companies chose to go with a system that combined versatility and ease-of-use, and that enabled them to quickly comply with FDA's micro testing requirements. The BioLumix system was a preferred choice early on, with the Soleris system gaining share in recent years. In total, these two systems, both of which are now owned by Neogen, have an estimated combined installed base of more than 500 systems in the DS/N segment. SCI research shows good adoption by companies in the U.S. as well as in Asia.

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Increased Awareness of Nutraceuticals

Published in January 2014, MarketsandMarkets' "Nutraceutical Ingredients Market by Type & Application—Global Trends & Forecasts to 2018" report covers five major applications of nutraceutical ingredients: functional food, functional beverages, dietary supplements, animal nutrition, and personal care. According to report, the aging population and an increasing number of chronic diseases generate health concerns in the consumers' mind, which are major factors that push the nutraceutical product and nutraceutical ingredients market. Consumers are shifting their eating habits from hunger-satisfaction to the intake of healthy food in order to either fulfill the nutrient deficiency in the body or to prevent the deficiency of major nutrients. Manufacturers are also taking in consideration the convenience factor for consumers and providing them with healthy nutrients in the form of food and beverages instead of supplements.

Different types of nutraceutical ingredients covered in the study are prebiotics, probiotics, amino acids, peptides and proteins, phytochemicals and plant extracts, omega 3 and structured lipids, fibers and specialty carbohydrates, vitamins, proteins, carotenoids and antioxidants, and others. The overall nutraceutical ingredients market is expected to experience growth rate of 7.2% from 2013 to 2018, whereas Asia-Pacific is expected to grow at a rate of 7.4% for the same period.—*FQ&S*

passed on to the consumer. For example, a standard can be established to assist manufacturers in producing interconnecting or interchangeable parts. Especially in high-tech industries, standards assure a manufacturer that if its product conforms, the product will interconnect with complementary or rival products of similar specifications. But most important in the days of the global marketplace is that industry self-regulation helps consumers evaluate products and services by providing information about the qualities and characteristics of the seller's products.

Filling a Need

In 2014, NPA's GMP Certification Program entered its 15th year of verifying for consumers that dietary supplements are manufactured according to the highest standards. Prior to the GMP final rule roll out in 2007, dietary supplement manufacturers were only required to adhere to GMPs for foods (21 CFR Part 110), which were largely enforced by local and state health departments. The association recognized that while food GMPs are certainly significant in regards to controlling general sanitation practices and monitoring sink log records, they did not address product quality with regard to specifications including identity, purity, strength, and composition, as well as incorporating process control and quality control features to prevent mix-up and contamination which could potentially render a product adulterated. NPA in conjunction with some of the other industry trade organizations helped develop a model for the GMP regulations and passed it to the FDA in late 1995. This model served as the basis for the 1997 FDA proposed GMPs in the form of an advanced notice of proposed rulemaking.

Rather than wait for the FDA to finalize the proposed rule, the association began developing its own GMPs to ensure quality. The NPA GMP audit program was launched in January 1999, with the first certifications issued in July of that same year. NPA's GMP education seminars were also rolled out in 1999. The program has awarded certification to more than 106 member companies, ranging from some of the largest manufacturers to the smallest in the industry, including both domestic and foreign firms, representing more than 45,000 finished products and thousands of raw materials.

When the program was first launched, the goal of the GMP Certification program was to ensure that all elements of the manufacturing process are reviewed so that products meet their intended quality. Third-party on-site inspections of manu-

(Continued on p. 22)

(Continued from p. 21)

More on Industry Education

NPA's GMP education sessions usually take place at industry events and tradeshows in the U.S., they have also been conducted for firms onsite domestically and in Asia, Europe, and South America. The education seminars have taught over 1,000 industry stakeholder firms as well as FDA regulators. NPA also holds monthly webinars in its "Wednesday Webinar" series on a variety of issues of interest to industry stakeholders—from GMP compliance, NDI notification, and adverse event reporting requirements, to didactic approaches on how to write and qualify structure/function claims. The organization is ensuring that the industry is properly trained and is manufacturing the best possible ingredients and products for consumers. NPA employs two of the FDA's former top heads in dietary supplement regulations and combines its experience in training the FDA field offices with the safety and quality record of the UL company.—*D.F. & C.H.*

facturing facilities cover such areas as filth control and cleanliness of equipment, facility, and grounds, establishment of a quality control unit, test methods, expiration dating, and procedures for storage and distribution. The third-party certification program includes inspections of dietary supplement manufacturing facilities to determine whether specified performance standards on a number of measures—including quality control, cleanliness, receiving, and testing of raw materials—are being met. A member supplier must receive an "A" rating in order to be certified. Those who receive either a "B" or "C" rating must correct deficiencies and submit for a re-audit.

Continued Improvements

The NPA GMP program was amended in 2008 to incorporate the requirements introduced in the long awaited FDA cGMPs Finalized Rule for dietary supplements (21 CFR Part 111). The program holds great value for the industry for a number of reasons but none more significantly than reducing exposure to regulatory vulnerability. It is important to note that a product failing to meet the FDA cGMPs is considered a technical adulteration. FDA will not provide help to a manufacturer or distributor to prepare for the GMP inspection, nor will it offer certification.

The objectives of the GMPs from the FDA's perspective are to provide the general public with unadulterated products that are not misbranded and meet their respective label claims. Thus, those manufacturing firms and distributors that seek to evaluate their state of compliance, have an expert third-party review their facility in preparation for an FDA inspection, or need very skilled and detailed assistance with their quality system to bring it to a state of compliance can use a third-party certifier to address that regulatory need.

To assist firms and present the 815-page GMP Final Rule in a more condensed, palatable form, NPA offers GMP education and training alongside the certification program. The seminar education has expanded to incorporate claims training to highlight the differences between permissible structure/function claims and unauthorized disease claims, New Dietary Ingredients, and requirements of various business models to the GMP Final Rule by former top agency officials.

NPA has recently partnered with UL, which has more than 100 years of experience in the testing and certifying of products. Its name is recognized universally by retailers, consumers, and suppliers of U.S. products, materials, components, and systems. NPA and UL are developing education to train both quality auditors and the dietary supplement industry. One problem with third-party auditing and certification bodies is the lack of transparency displayed so firms can know the true quality of their auditors. NPA and UL are developing unique training in GMPs, Safe Quality Foods, and new changes with the Food Safety Modernization Act designed specifically for auditors. The process in how auditors are qualified to perform quality audits will provide much needed transparency and enable auditors to better think like agency investigators.

Third-party quality audits are a tool that should be used more in the dietary supplement industry as a management tool for determining the effectiveness of one's quality systems in place. There is no excuse for failing to meet FDA cGMPs. A plethora of resources is available to ensure firms are compliant. Don't risk falling victim to an avoidable mistake—take advantage of resources that have regulatory experience to help navigate your way through compliance. ■

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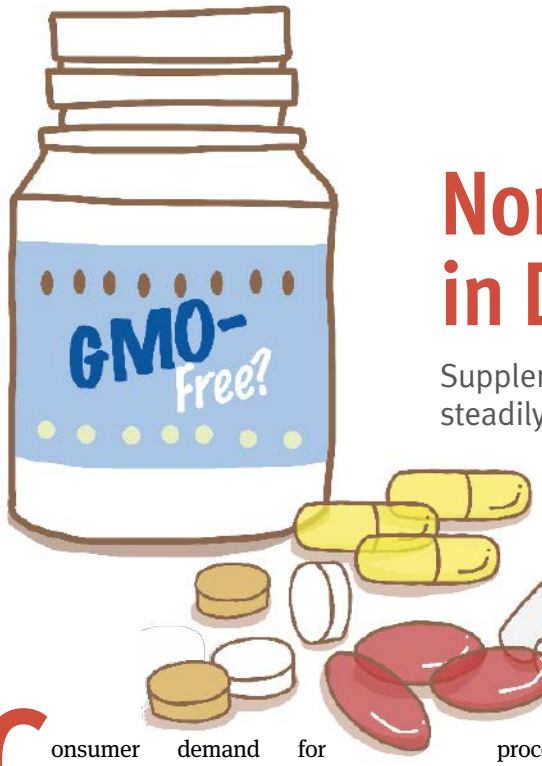


Non-GMO Verification in Dietary Supplements

Supplement companies seeking non-GMO designation are steadily catching up with the food and beverage sectors

BY **KELLY MAE HEROUX**

Consumer demand for non-genetically modified organism (GMO) products is rising globally, alongside the emergence and growth of both mandatory and voluntary non-GMO labeling initiatives. The benchmark for these new programs was set in 2004 by Europe's GM labeling regulations, BC 1829 and 1830, which gave rise to the Ohne Gentechnik, Nourri Sans OGM, and Gentchnik-Frei programs. North America's non-GMO verification program is implemented and managed by the Non-GMO Project (NGP).

Global sales of non-GMO products are projected to increase dramatically over the next five years to encompass fully 15 percent of all global food and beverage retail sales in a market currently valued at over $800 billion. According to the Natural Marketing Institute (NMI), the package claim "No GM ingredients" plays a major role in consumer purchasing decisions. In fact, that claim was concluded to be more important to North American shoppers than "great tasting" and "nutritious." Due to this sharp increase in consumer interest, NGP Verified has become one of the fastest growing labels in the natural products industry. To date, more than 20,000 products have been NGP verified, representing $7 billion in annual sales.

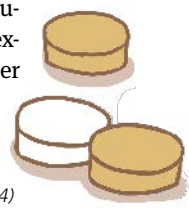
Along with national and global interest in non-GMO products comes an uneven playing field for non-GMO product manufacturers. Non-GMO standards and regulations, which focus on traceability, segregation, and the testing of high-GMO risk inputs, vary by country, region, and state. Some are process-based and investigate inputs and processing aids, while others are based on the finished product. The common feature across all countries with labeling laws is a requirement that products with GM-derived content that is not substantially equivalent to its conventional counterpart *be* labeled. For companies in the dietary supplement industry, meeting the core requirements of any non-GMO scheme can be very challenging. According to Kiren Israelsen of the United Natural Products Alliance, "The supplement industry lags behind the food industry on being non-GMO."

Unlike the majority of food and beverage products, supplements commonly include long lists of ingredients. The bulk of these ingredients are high-GMO risk, being highly processed, animal derived, or sourced from high-GMO risk crops. Thus, demonstrating compliance for just one of this type of ingredient can be laborious. A manufacturer seeking NGP verification for a product containing lanolin derived D3 (cholicalciferol), for example, would have to secure documentation from their supplier that the sheep from which the lanolin was derived were not fed GM feed, which requires review of feed ration statements. Vitamins B12, B2, beta carotene, and ascorbic acid among other vitamins, amino acid and enzymes may also be manufactured using GM microorganisms, in which case, evidence that the microorganisms used to produce these ingredients are non-GMO would be required, along with evidence that the substrate with which the microorganisms were cultured was non-GMO. Other common GMO-risk ingredients found in supplements include solvents, enzymes, carriers/standardization materials, and gel caps/animal derived gelatins.

Adding to the inherent challenge of verifying long lists of ingredients as non-GMO is a lack of transparency in supply chains and subsequent difficulty in procuring the necessary documentation from ingredient suppliers. These documents include: disclosures of formulation percentages (for high GM-risk ingredients); process flowcharts to identify raw material sources; non-GMO declarations of enzymes and fermentation organisms; country of origin information for raw material sources and production processes; and traceability and segregation practices. Acquiring this level of detail from what is oftentimes a large international manufacturer with proprietary processes can be a stretch for supplement producers.

However, many efficient pathways through verification have been developed. For example, FoodChain ID, the founding technical administrator to NGP, has developed guidelines, ingredients forms, and absence declarations, and, in addition provides consulting to help participants in the evaluation of supplement products.

In tackling the requirements of complex ingredients and supply matrices, the supplement industry has been encouraged by single-attribute label trends. Single-attribute label claims communicate transparency, are explanatory, and build consumer confidence by being third-party based. NMI reports that shoppers are increas-



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ingly seeking specialized consumables to meet their lifestyle and dietary needs. In doing so, they look to front-of-package single attribute claims to avoid the burden of having to read the fine print on the back. Some believe that these claims surpass brand loyalty.

Though NGP verification is achievable, it's not always easy; some products have taken more than a year to demonstrate compliance. The Non-GMO Dietary Supplement Working Group was launched in an effort to even the playing field and assist any supplement company in becoming eligible for non-GMO verification. Cofounded by MegaFood's CEO Robert Craven and FoodChain ID, the Working Group consists of industry professionals who share knowledge of ingredient suppliers, reformulation strategies, and general guidance in preparing for verification. The following are some examples on how to prepare for non-GMO verification.

Consult with a qualified technical administrator or verifying body prior to joining the non-GMO scheme to identify risk, foresee obstacles, and get practical solutions. This reduces costs and fosters awareness of what to expect once enrolled.

Collect supporting documentation prior to enrolling. Use a standardized data collection tool for all ingredients, such as forms used by a technical administrator. Relevant data includes disclosures of additives, carriers, enzymes, microorganisms, fermentation media, raw material sources, and non-GMO manufacturing systems.

Stage the enrollment of products by beginning with bestsellers or product formulas that capture a range of the high-GMO risk ingredients in your product line. A staged enrollment helps familiarize staff with what's required from ingredient suppliers; eases severity of the learning curve and lessens workload of your quality department; and determines the level of transparency and open communication channels from ingredient manufacturers.

Appoint staff with adequate resources and education to accommodate the additional workload. Non-GMO designation for a product is not a one-time effort. Standards evolve, GMO approval and commercialization statuses change, and GMO testing requirements and tolerance thresholds change due to new GMO events.

Team with an accredited non-GMO scheme approved testing laboratory if testing is deemed a requirement for verifying high-GMO risk inputs. Testing and sampling requirements vary according to differing ingredient matrices. Identifying the most efficient point in the supply chain for capturing qualified representative samples is crucial to keeping costs down.

Develop new products with a consideration toward demonstrating compliance with your chosen non-GMO scheme(s), and then consult with a technical administrator prior to enrollment to pre-evaluate the new formulation for eligibility. Manufacturers who do this can have their new products successfully verified in less time while avoiding costly missteps. ■

Heroux has served as technical consultant for prospective participants in the Non-GMO Project Product Verification Program, and is currently a manager for FoodChain ID, which is part of the Global ID Group family of companies. Reach her at kmheroux@foodchainid.com.

REFERENCES FURNISHED UPON REQUEST

Figure 1: Components of an effective environmental monitoring program.

AIB

Improving Environmental Controls

How to design an effective environmental monitoring program that is capable of detecting signs of microbial contaminants as early as possible | BY **LAKSHMIKANTHA CHANNAIAH**

The ability of pathogenic microorganisms to gain entry into food supply systems remains a major public health challenge, and concern. Each year, foodborne illness outbreaks affect millions of people and kill thousands. Additionally, these outbreaks undermine consumer confidence in affected products, and diminish market demand. A substantial amount of these outbreaks results from poor environmental controls and/or hygiene practices. It is critical to maintain and monitor the hygienic environment in the food processing facility for the production of safe food products.

An environmental monitoring program (EMP) collects information about the specific environmental conditions and provides vital information about indicator microorganisms as well as pathogens in a timely manner. Additionally, EMP will evaluate the effectiveness of a plant's hygienic practices. The EMP is not designed to validate the effectiveness of cleaning and sanitizing methods, but is more focused on validating cleaning and sanitizing frequencies, and other Good Manufacturing Practices (GMPs) (21 CFR).

Objectives and Corporate Commitment

It is important to clearly state EMP objectives. The EMP team should have clarity on target indicator microorganisms and pathogens to determine sanitation cleaning frequency, to initiate appropriate corrective actions, and to reinforce employee training programs. Also, corporate management needs to understand and support the EMP by supplying all the required resources to ensure that it is an essential part of the food safety program. The objectives, risks, and associated corrective actions should be properly communicated to all the employees or at least to the EMP monitoring team.

Components of an Effective EMP

An EMP should be carefully designed after evaluating the facility, the type of processing, raw materials, pathogens of concern, finished products, packaging, and shipping. Some key components that should be a part of the EMP are an environmental monitoring team, zones, sampling, selection of indicator and pathogenic microorganisms, sampling tools, labeling and shipping, baseline/target, trends and corrective actions, and mapping (Figure 1).

EMP Team

The first task in the implementation of an effective EMP is to bring together individuals familiar with the operation to help identify potential areas of risk and concern in a facility. This group will be the EMP team and may include the plant qual-

(Continued on p. 26)

(Continued from p. 25)
ity manager, the plant or corporate microbiologist, line supervisors or operators, and sanitation supervisors or workers. If the facility does not have a food safety microbiology expert experienced in the development and implementation of an EMP, it is strongly recommended that the facility contact an experienced outside expert for guidance. Once the team is assembled, the process flow should be evaluated to include the zones posing the most microbiological risk to the finished product. The team should walk the plant floor to identify areas where the product may be vulnerable to contamination.

Zones

The best way to identify sampling points is to use the zoning concept, which divides facility operations into four zones based on the levels of risk. It is vital for the environmental monitoring team to define zones 1 to 4. Once the zones are determined, carefully consider which specific tests are going to be used before beginning sampling.

Zone 1 refers to all direct food-contact surfaces in the plant (e.g., blenders, conveyors, utensils, work tables, etc.). It is not recommended to swab for pathogens in zone 1 because it is not an effective way to capture product contamination. Non-pathogen or indicator microorganism swabs should be used on product surfaces that are not always cleanable, like the underside of a conveyor or a filling chute that is stationary.

Total percentage of testing from zone 1 is normally 10 to 20 percent.

Zone 2 refers to nonfood-contact areas that are closely adjacent to product-contact surfaces. In general, this is the area where environmental contamination is most likely to affect the safety of the product (e.g., equipment framework, maintenance tools, drip shields and chain-guard housings, etc.). The focal point of zone 2 testing will be to validate sanitary design of the equipment. These are the areas in the framework that collect food particles, but are not easily broken down for proper cleaning.

Total percentage of testing from zone 2 is normally 40 to 50 percent.

Zone 3 refers to nonfood-contact surfaces that are not close to zone 1 surfaces (e.g., walls, floor, drains, air handling units, etc.). If zone 3 is contaminated with a pathogen, it could lead to contamination of zone 2 through employees' actions or movement of machinery. Zone 3 monitoring will indicate if there is a weakness in building design or poor employee sanitary practices. Areas of concern might include buildup in overheads, around extraction units, around ventilation fans, or floor areas, and handoff between sanitation and production, maintenance and production, employee entrance and production, or storage (freezers/coolers/dry) and production.

The total percentage of testing from zone 3 would be around 30 to 40 percent.

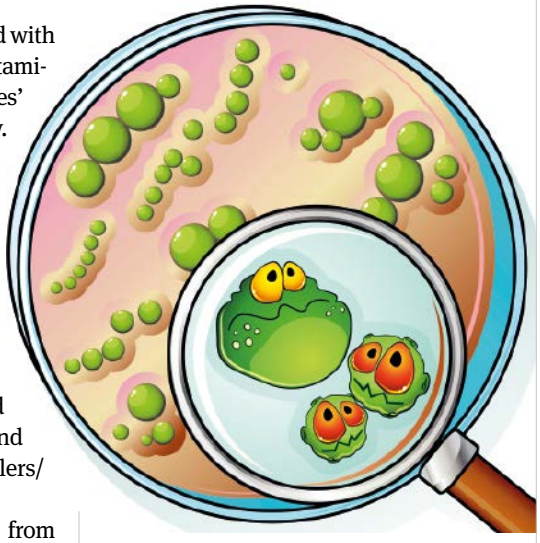
Zone 4 refers to the areas remote from product processing areas (e.g., office areas, locker rooms, maintenance rooms, etc.). If zone 4 is not maintained in a good sanitary condition, it can lead to cross-contamination of zones 1, 2, and 3. Zone 4 is not considered a high risk of potential cross-contamination.

> An EMP should be carefully designed after evaluating the facility, the type of processing, raw materials, pathogens of concern, finished products, packaging, and shipping.

Apart from zones 1 to 4, periodic air, office areas, water, and plant employee hand swab samples should be monitored for indicators as well as pathogens. Zone 1 could also be tested for pathogens. However, if zone 1 is tested positive for pathogens, then the product made on that line must be held until further confirmative test results are available. If the final confirmative results are positive, then it is likely a recall situation.

Using Indicator Microorganisms

Indicator microorganisms are routinely used to determine the potential presence of pathogens and to assess the effectiveness of cleaning and sanitation practices.



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Some benefits of using indicator microorganisms include:

- Non-pathogenic and sophisticated containment facilities or labs (e.g., Bio Safety Level-2) are not needed for sample analysis,
- Low concentrations of pathogens in the environment make them difficult to detect using current testing methods,
- Indicator microorganisms are high in numbers and can be easily enumerated,
- They are valid representation of pathogens of concern since they use nearly the same pH, nutrients, temperature, water, etc. as pathogens, and
- Laboratory tests are generally faster and less expensive.

Examples of indicator microorganisms that can be used to monitor hygienic conditions in an EMP are total aerobic plate count, total coliforms, fecal coliforms, and *Enterococcus spp*. of fecal origin. Indicator microorganisms are *not* a substitute for testing pathogens. A positive result indicates conditions for pathogen contamination and a risk of foodborne illness is plausible.

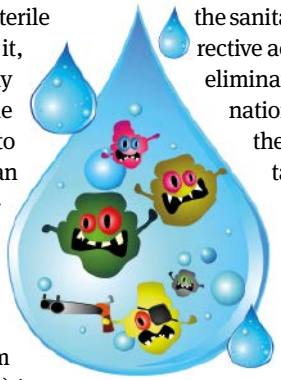
Sampling and Frequency

Environmental information or data is obtained using a vast spectrum of approaches, ranging from a simple settling plate (sedimentation), to sophisticated indicator swabs that forecast the presence of specific pathogenic bacteria in a given establishment. There are a number of methods and tools that can be used for environmental monitoring. The choice of methods/tools depends on the type of

facility, type of food products, pathogen of concern, etc. The common sampling tools that can be used to evaluate the overall sanitary condition of the facility includes sterile swabs, sponges, air sampling units, RODAC plates, ATP (adenosine triphosphate) bioluminescence assay kits, etc. More sampling and testing does not necessarily mean more safety. Always follow hygienic procedures (e.g., wear sterile nitrile gloves) while collecting environmental samples. Determining frequency of sampling (daily, weekly, biweekly, monthly, quarterly, etc.) and the time of sampling (at what time during the shift) are the most vital parts of the EMP. Once the EMP is fully implemented it should be verified for its effectiveness. If the current sampling plan and frequency fails to meet the expected result, then the frequency and number of samples per zone should be modified to achieve the target.

Labeling and Shipping

The environmental monitoring team should receive proper training on sampling. Microbial supply companies or accredited laboratories will often come to your facility on an annual basis to train and calibrate sampling tools. Once the environmental samples are collected, write the sampling date, location, device used, sample size, list of testing requests, date submitted to the lab, etc. on the sampling bag for easy identification. Always submit a negative control swab (i.e., a swab not being used). Also, it is important to ship the collected samples as soon as possible (overnight shipping) in a sterile plastic bag with ice packs in it, but keep the ice from directly contacting the outside of the sample bags. It is important to keep the samples cool (less than 40 degrees Fahrenheit) to prevent microbial growth.



Baseline/Target

Historical data (e.g., consecutive sampling results/data from the previous six to 12 months) is needed to establish a baseline/target. For example, if a site tests less than 50 cfu (colony-forming units) for a year with only two/three spike readings, then a 50 cfu would be set as the baseline. Justification for a baseline higher than 125 percent of the mean (e.g., seasonality adjustment) should be documented. The EMP and the target/baseline are unique for each plant and for each type of product. Also, it is different for different zones. Since the reasons for a positive finding are likely to be plant-specific, the corrective actions will differ from plant to plant based on final food products. The environmental monitoring team needs to consider variables that can impact the baseline (e.g., seasonality, geographic differences, and supplier sources).

> Indicator microorganisms are routinely used to determine the potential presence of pathogens and to assess the effectiveness of cleaning and sanitation practices.

Trends and Corrective Actions

The results of environmental monitoring samples should be tabulated in a way that they can be compared with previous results in order to highlight trends. It is important to compare sampling results against a target level or a baseline. Any increase in indicator microorganism or pathogen numbers should be addressed by corrective action, since these results are a signal that there is a deviation in the sanitary conditions. A suitable corrective action (e.g., identification and elimination of the source of contamination) should be initiated to bring the values close to or below the target/baseline.

If a positive result (or repeatedly high numbers) is found in any sampling zone, reassemble the team and initiate a root cause investigation. Restrict traffic in the affected zone(s) as much as possible. Examine the area thoroughly and use the team's findings to improve operations, including: increase cleaning and sanitation frequencies, conduct repairs (water leakage, drains, etc.), change employee traffic patterns and practices, collect more swab samples, initiate corrective actions, verify the effectiveness of corrective actions, and monitor the results. Most environmental monitoring programs do not consider the corrective action to be successful until there are at least three consecutive negative results from the affected area after it has been verified that something was changed to address the microbial contamination.

Mapping

Every facility has several areas to map, and within each area, there will probably be two or three different zones. For example, a plant might have a couple of raw areas (coolers, blending rooms), fully processed areas (oven exit, cooling tunnel), and packaging areas (baggers, form-fill, packing tables). A map of all sampling locations should identify each area and the specific zones within each area that will be tested. This can be an effective way to identify hot spots to take appropriate corrective actions. Map the locations of negative results (green flag), increasing trends (orange flag), and positive samples/results (red flag) on a facility design diagram to help define the scope of the problem. Mapping helps identify harborage niches and hot spots in a plant that may act as a source of contamination.

Summary

An effective EMP is an essential component of a food processing system. FDA's Food Safety Modernization Act advocates the importance of implementing an effective EMP in food manufacturing facilities as a preventive measure to detect areas of pathogen harborage and to verify the effectiveness of cleaning and sanitation programs. It is critical for food manufacturers to develop a science-based environmental sampling, testing, and verification program that effectively monitors the overall hygiene quality of the facility. An unscientific and improperly designed EMP can be expensive and wasteful. Every product, process, employee training, raw material, GMP, and pathogen of concern is different. EMP is specific to the individual food facility and to the individual operations within the facility. ■

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How to Fit Training into Your Production Schedule

Providing food safety training for when new employees are onboarded to a company

BY **JENNIFER MCCREARY** AND **MARIE LEFAIVE**

Editor's Note: *This is the first in a five-part series of articles that will explore each concept behind the five moments of need in training.*

When it comes to workplace learning, Conrad Gottfredson, PhD, and Bob Mosher, two well-known performance support experts, have defined five distinct moments of need:

1. When learning for the first time,
2. When learning more,
3. When remembering and/or applying what's been learned,
4. When things go wrong, and
5. When things change.

When you know these five moments, it is easier to see how you can fit training into your production schedule. We're starting this series with the need for training when people are learning for the first time, and in the coming months, we will take a closer look at each of the other moments.

The classic example of this type of learning is onboarding training for new hires. The goal is to help employees acquire the necessary knowledge, skills, and behaviors to become productive workers. In the food industry, we can include an additional goal: helping them become safe food workers. There's no need to reiterate why you do not want your company to suffer through the misery of a recall. Ensuring new employees clearly understand their responsibilities is crucial.

It is a lesson that was learned the hard way by a major bakery facility. The company decided it was unnecessary to invest in food safety training for temporary hires as they were only employed in the packaging room. The day the company found a temporary worker with a pocketful of peanuts and had to destroy the full shift's production is the day it revisited that decision.

Contrast this to a company that has developed a full complement of onboarding programs, from food safety training for contractors and visitors, to introductory food safety training for all staff, to specialized streams for supervisors and line personnel. Simple, to-the-point programs delivered by trained internal staff has ensured that the food safety awareness is woven into every person's DNA the moment they enter the facility.

What Must Be Included

Basic Good Manufacturing Practices (GMP) training for all employees is critical. It remains the best line of defense against the introduction of unnecessary hazards. GMP training covers the daily activities associated with food safety programs: health and hygiene, cross-contamination avoidance, sanitation, tools, and equipment. Your company's food safety policies, standards, and expectations must also be included. For those with more direct food safety job responsibilities—for example HACCP (Hazard Analysis and Critical Control Points) team members or CCP owners—training must include topics such as monitoring, corrective action procedures and risk assessment.

A word of caution: Do not overload your new hires. Trying to cover every detail of every practice or procedure in a company's arsenal is counter-productive. New employees are in a stressful situation, which means they are not optimally primed to learn new things. When they are bombarded with information, they will not be able to take it all in. It's most likely that, by the end of training, new hires will have forgotten most of the information that was presented. The following actions can address this problem.

Start as early as possible. Send out any introductory food safety material, either online or printed, before the new hire even begins work. This serves the dual purpose of introducing the person to concepts of food safety and ensuring that the importance of this topic is quickly underscored.

Provide a blend of training channels. Classroom training is important, but when it is teamed with peer coaching, virtual discussion boards, or an online information portal, the effectiveness of training increases dramatically. Remember that training is not just about teaching someone new information; it's about showing them how to find answers when they have questions.

Scatter the training over several days or weeks. This will allow new hires time to become competent in one learning area before moving onto the next. It may mean a slightly slower time to competency, but the savings in terms of retraining costs is worth it.

Importance of Consistency and Context

If your onboarding process is haphazard, it lacks quality control. Some sessions will be excellent, others will be dismal. Any new hire who happens to arrive on a dismal day is guaranteed to have significant learning gaps. Schedule food safety training along with other job-specific training, as well as general company onboarding.

If your onboarding programs lack context, you are probably checking off the training box without realizing any true be-

havior changes. Telling employees that they must not walk between the raw and processed sections of the facility is a good directive; not telling them *what* could happen if they do and *why* it is so important to the business is a bit like telling people not to go swimming in the lake without telling them that there are leeches in the water.

Who Should Deliver the Training

If it is in your budget to hire professional trainers, then by all means do so. For those whose budget is less generous, onboarding training can be done in-house or in combination with professional trainers. Two keys to success are as follows.

1. The training must be properly designed with attention paid both to the accuracy of the content and the pace of the program. It should be built following adult learning principles that provide active learning opportunities and plenty of time for practice. Lectures were rarely successful at teaching us in our school days. They are no more successful today.

2. The training must be delivered by competent people. This means people who are not only knowledgeable of the topic, but who have had some grounding in the craft of training. Expertise in a subject is not enough—in fact, experts are often very poor onboarding trainers because they simply cannot chunk the information into simple, easy-to-understand lessons. It is not an understatement to say that the success of a training program can rest with the quality of the trainer.

Determining Competence

The proof of training is in the doing. When an employee demonstrates proper food safety practices, you know the training has been successful. There are, however, levels in the assessment process that can help determine competence.

- Level one is a check for understanding: Has the employee learned the information? Most companies use quizzes to test for this, though a one-on-one discussion is often more useful at uncovering misconceptions.
- Level two looks at ability: Can the employee perform a task as demonstrated? Watching someone do the work in their natural work setting is the best test for this level.
- Level three assesses attitude: Does the employee believe what you have taught and recognize its importance? This can be evaluated by listening to a new hire explain concepts or, as in level one, by having a conversation.

Think of when you learned how to drive. The first step was the written exam to prove you knew the rules of the road. The second was a road test to show your skill behind the wheel. The third is one you demonstrate each time you choose not to drink and drive.

And of course, it goes without saying that any training must be fully documented. After all, if it isn't written down, it didn't happen.

Finally, a successful onboarding program requires frequent follow-up to make sure new employees understand their jobs, know where to go for help, and are integrating with the team. It takes a long time to become a part of a new culture. Be patient, and give your new hires the support they need over the first few months on the job. ■

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Sweet and Savory: Popular Ingredients with Possible Lawsuits

FDA's proposed rules and guidelines on the two most common food additives—sugar and salt—present a number of challenges to manufacturers

BY **MICHAEL GRUVER** AND **GLENN POGUST**

Few ingredients are more common in American food products, or more popular with American consumers, than sugar and salt. Indeed, the average American consumes 3,400 milligrams of salt and 110 grams of sugar every day, amounts well in excess of those recommended in the Dietary Guidelines for Americans issued by the U.S .Department of Health and Human Services in conjunction with USDA. More than just popular, both ingredients are extremely useful to food manufacturers. Sugar, for example, allows for longer shelf-life while adding bulk and color to processed foods. The preservative effect of salt has been known for thousands of years, but salt also serves to reduce cost in comparison to other flavoring agents while masking unpalatable flavors associated with processing. Given this combination of utility for industry and popularity with consumers, there should be little surprise that both sugar and salt maintain a constant presence in the American diet.

For food manufacturers, though, the near future may hold a number of challenges where sugar and salt are concerned. In particular, recent U.S. FDA action implicating sugar and salt, combined with increased willingness on the part of plaintiff lawyers to pursue labeling and ingredient claims against food manufacturers, could lead to an environment of increased cost and litigation across the industry.

Will Sugars Lead to Litigation?

Following the passage of the Food Safety Modernization Act, or FSMA, in March 2014 the FDA proposed a number of changes to the Nutrition Facts Panel on packaged food, including the partition of information on sugar into total "Sugars" with a separate category termed "Added Sugars." In proposing this change, FDA relied on authority provided in the Food Drug and Cosmetic Act that allows changes to the Nutrition Facts Panel to help consumers "maintain healthy dietary practices." According to FDA, including Added Sugars will "help consumers understand how much sugar is naturally occurring and how much has been added to the product" with the premise that added sugars "provide no additional nutrient value..."

The Added Sugars proposal raises a number of questions and concerns. For one, as proposed, the category of Added Sugars includes any type or amount of sugar added to foods during processing or preparation, failing to distinguish between the addition of raw untreated sugar products, common refined sugar, naturally-occurring sugars from whole food sources such as fruit juice, and modern, highly synthesized ingredients such as high fructose corn syrup. To the FDA, the fact that sugar is added appears more important than what is actually being added. Indeed, the FDA acknowledges its rationale for making added sugars a mandatory declaration "is different from our rationale to support other mandatory nutrients to date," and that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease.

It is also not clear whether information on Added Sugars is truly helpful to consumers, or just likely to cause confusion. One study, published in August 2014, tested consumer perceptions of the relationship between total carbohydrates, sugars, and added sugars, and investigated how consumers use the Nutrition Facts panel to make purchasing decisions. Shown different versions of the Nutrition Facts panel, 92 percent of consumers were

able to correctly determine how much sugar was contained in the product when using the current Nutrition Facts panel, while only 55 percent and 66 percent of consumers were respectively able to determine total sugar content when shown a panel with Added Sugars information. According to researchers: "34 percent believe [Added Sugars] simply means more sugar has been added to the products, 28 percent think the line distinguishes between added sugars and sugars that are naturally occurring in the other product ingredients, [and] about one in five (19 percent) just don't know what it means."

From a litigation perspective, the most troubling aspect of the Added Sugars panel is the potential for this new labeling requirement to provide fodder for food labeling lawsuits. Given the lack of reliable evidence on the health effects of Added Sugars as opposed to total sugar intake, it is unsurprising that the FDA has thus far declined to provide guidance to food manufacturers on the proper protocol for measuring and establishing which sugars are "added." What is more, FDA acknowledges: "[T]here are currently no analytical methods that are able to distinguish between naturally occurring sugars and those sugars added to a food."

In lieu of reliable analytical methods for measuring added sugar content, the FDA proposes new mandatory record-keeping procedures that would allow regulators to verify that the Added Sugar content reported on the label matches up to the sugars added according to a food manufacturer's production protocols. FDA could, in theory, take action against a food manufacturer who fails to maintain adequate records, even if there is no affirmative evidence that the product in question was mislabeled. Such an approach, in turn, leaves plaintiffs free to file suit by arguing that the manufacturer misled the public in reporting a specific Added Sugar content, when in fact the manufacturer could not verify that the reported amount was accurate. Under this approach, FDA's record-keeping policies potentially turn manufacturers into defendants.

The Added Sugars declaration could also lead to litigation against manufacturers of food products that contain multiple sweetening agents, particularly if naturally-occurring sweeteners such as fructose are involved. While the FDA notes that certain products such as soda will contain only added sugars, its simplistic Added Sugars model makes no mention of how to sort between multiple ingredients that all contain some type of sugar.

Consider a hypothetical juice product made from 90 percent grape juice and 10 percent pineapple juice. The manufacturer, not unreasonably, considers sugar in the grape juice inherent in the production process and sugar from the pineapple juice to be Added Sugar, and the labeling reflects this view. In a case like this, however, the FDA provides no standards as to how the manufacturer should determine which are the inherent sugars and which are the Added Sugars. A skilled plaintiff attorney is free to file suit claiming that the product is mislabeled, either on a theory that the inherent sugars should actually be reported as Added Sugars, and vice versa, or that all of the sugars in this product should be reported as Added Sugars.

The Added Sugars declaration could also lead to litigation against manufacturers of food products that contain multiple sweetening agents...

This problem is even more pronounced if one considers another hypothetical juice product made from equal parts of 10 different types of juices, similar to a number of currently popular brands. Which of the 10 potential sources of sugar are Added Sugars? Likewise, imagine a cereal in which sucrose is added to the cereal flakes, and then later in the production process apple juice is added for flavor. Is the fructose from the apple juice an Added Sugar, or is it only the sucrose? If the manufacturer fails to include the fructose as an Added Sugar, have they mislabeled its product? The only certainty is that the FDA has thus far given no indication to manufacturers how to handle this issue, leaving manufacturers to guess on the right approach and plaintiffs free to argue that a different approach should have been followed.

Salt: Lower Levels or Else?

In June 2014, a few months after FDA presented its Added Sugars proposal, the Administration announced its intent to issue voluntary guidelines for food producers to reduce sodium levels. While FDA has not put forward any timeline for these guidelines to be released, the public was told to expect them "relatively soon."

The impending new guidelines raise a number of potential issues for food manufacturers. First and foremost is the question of whether a manufacturer should try to comply with the guidelines, given that they are not mandatory. While reducing sodium content would likely enamor a manufacturer to the public community and regulators, a significant drawback to voluntary sodium reduction is the potential to fall behind in the marketplace. Sodium plays a key function in many foods, improving texture, color, and controlling for microbes. Maintaining those qualities while reducing sodium is a significant obstacle for a manufacturer, and consumer reaction to reduced sodium levels is often negative. For example, a 2010 initiative by Campbell's Soup to reduce sodium content was well-received by public health advocates but fared poorly with consumers. In 2011, Campbell's added the salt back.

If consumers do not generate demand for sodium reduction in their purchasing preferences—which has the effect of punishing manufacturers who voluntarily reduce sodium in their products—what reason is there for a manufacturer to make a meaningful reduction short of an FDA mandate? One significant motivation for voluntary compliance is the potential that industry-wide refusal to comply with the new guidelines—or the refusal to at least make a serious attempt to comply—could give FDA no option short of issuing mandatory sodium reduction regulations. It seems apparent from both the Added Sugars initiative and the forthcoming sodium reduction guidelines that the current environment at FDA is one in which food manufacturers will not be granted the benefit of the doubt, and initiatives favored by "consumer advocates" may be adopted by FDA even if the science behind them is not yet well-established. Given this regulatory climate, industry may be wise to avoid putting FDA into a position where it is left

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with no choice but to mandate sodium reduction.

It is also worth noting that the FDA has more than one way to force manufacturers to lower sodium levels. While a direct mandate identifying maximum allowable sodium content is the most obvious course, FDA could also pursue indirect methods, such as modifying or eliminating sodium's GRAS status. When FDA first formulated the GRAS list in 1959, it did not formally list salt as a GRAS ingredient. The reason was that FDA judged it "impracticable" to formally list all GRAS substances, and named salt, along with pepper, vinegar, and baking powder as examples of "common food ingredients" that were considered safe and presumed to be GRAS. From a regulator's perspective, then, the GRAS status of sodium has always been presumed, never scientifically established. Indeed, a 1979, a report by the Select Committee on GRAS Substances concluded that: "The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced." The framework exists, then, for FDA to undertake a review of sodium's GRAS status, and eliminate that status if so inclined. While stripping sodium of its GRAS status represents something of a "nuclear option" for FDA, it is nonetheless an option available to the Administration to reduce sodium levels in processed foods. Accordingly, some amount of cooperation with the FDA on sodium reduction would seem an ideal path for food manufacturers rather than risking the imposition of new regulations entirely from above.

Working with FDA could lead to novel approaches that benefit all parties. From a health and regulatory perspective, one concern for both sugar and salt are the levels of each ingredient found in foods not typically associated with them. One potential way for industry to address this concern while protecting its own interest is to focus regulators on a narrower field of products where sodium reduction would be most beneficial. Potato chips, for example, are an obvious high sodium food where the salty taste is at the heart of consumer appeal. Mandating reduced sodium levels that would apply to products like this is a questionable use of limited resources both among regulators and industry. Accordingly, the two sides could work together to identify this and other obvious high-sodium foods for exemption to sodium reduction standards, perhaps including notice or warning that the sodium level in that product exceeds the amount recommended in the government's Dietary Guidelines.

Potato chips, for example, are an obvious high sodium food where the salty taste is at the heart of consumer appeal.

There are also commercial advantages to treating the voluntary sodium reduction guidelines as if they presage a mandate. Manufacturers who investigate lower sodium alternatives to their current products will have the advantage of using this time to develop products that consumers will find more palatable despite their lower sodium content. When lower sodium levels are mandated, a manufacturer who is prepared could enjoy considerable advantage over the competition if its low-sodium lines are store-ready while competitors are still working to comply with the new standards.

FDA's Isolated Approach

One thing that should not be lost in focusing on the FDA's sugar and salt initiatives is the fundamental question of whether an ingredient-by-ingredient approach to food regulation is most beneficial for consumers. A significant amount of research suggests that high blood pressure, typically associated with Americans' high sodium diet, is more a result of the overall low potassium intake in the U.S. In other words, the problem is not that Americans eat too much salt, but that they eat too few fruits and vegetables and other foods high in potassium. This may explain why, on average, people in countries such as Italy experience fewer cardiovascular problems than Americans do, even though its average salt intake is significantly higher than in the U.S. It also highlights the inherent limitations of regulating ingredients in isolation, and ignoring the potential that health effects associated with specific ingredients may also depend on the balance of those ingredients against other substances in the human body.

Political realities, and public relations, may make it easy to pursue regulation of certain ingredients and industries. But if the FDA is truly concerned with promoting a "balanced" diet, it should remember that balancing involves evaluating all of the variables against one another simultaneously. Picking at ingredients one-by-one without keeping the entire system in mind may ultimately increase the risk that consumers will develop the poor health conditions that FDA is attempting to curtail. ■

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BROOKFIELD ENGINEERING

Brookfield CT3 Texture Analyzer.

Compression and Tension in Measuring Physical Properties

Various types of fixtures can be used to perform everyday QC tests for food and packaging materials

BY **ROBERT MCGREGOR**

Texture analysis is the science that measures the mechanical properties of food products and correlates these findings to the way that human beings use their senses to evaluate foods. More than 65 years of research have resulted in a set of definitions that relate peoples' sensory properties to instrumental measurements based on a standard test known as Texture Profile Analysis or "TPA."

Food Products

The image above shows an example of a texture analyzer with cylinder probe used to measure the firmness of sliced bread. The TPA test is a two-cycle procedure that pushes the probe into the bread a defined distance, measures the resistant force, pulls back out, then repeats the same compression cycle. Figure 1a shows the graph of force versus time for the two-cycles; force is on the y-axis, time is on the x-axis. Note that the peak load P1 in the first cycle is higher than the peak load P2 in the second cycle. Once the bread compresses during the first cycle, it does not fully recover to its original position. The texture analyzer records the probe position and the force load is measured throughout the TPA test, which generally takes less than 30 seconds to perform. Figure 1b shows an alternative way to present the same data using distance (position of the probe) on the X-axis. These measurements are used in mathematical calculations that define properties of the sliced bread, such as "springiness" and "chewiness."

Table 1 on page 34 lists the defined properties that can be quantified with measurements from a texture analyzer. The two primary characteristics are "hardness" and "adhesiveness." "Hardness" is exactly what it sounds like—how firm is the object that is under compression. French bread with a crusty exterior will give significantly more resistance to the probe compared to the sliced white bread. "Adhesiveness" is the amount of work required to extract the probe from the food item. Another way of thinking about this is how sticky the food item might be and how difficult it is to pull the probe away. For bread there is no resistance when the probe is extracted, but for salad dressings there can be noticeable resistance.

Using the data related to the hardness and adhesive force measurements, other parameters such as "springiness" and "chewiness" are calculated. Note that "springiness" is exactly what you might think—how much does the bread spring back after being compressed. "Chewiness" on the other hand is an expression that you instinctively understand, but the mathematical calculation shown in the Table may seem complex—the product of hardness, corrected cohesiveness, and

(Continued on p. 34)

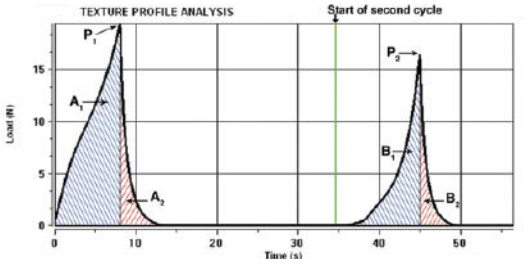

Figure 1a: Graph showing force load vs. time for texture profile analysis test.

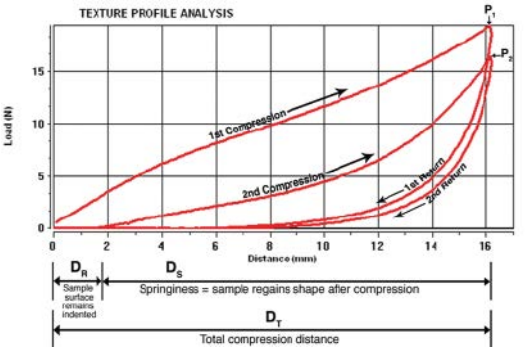

Figure 1b: Graph showing force load vs. distance for texture profile analysis test.

PARAMETERS[1]	SENSORY DEFINITION	INSTRUMENTAL DEFINITION	
Hardness	Force required to compress a food between the molars. Defined as force necessary to attain a given deformation.	Peak force of the first compression cycle.	P_1
Springiness Index Preferred for comparing samples of different lengths	Ratio of the height the sample springs back after the first compression compared to the maximum deformation.	Springiness divided by total deformation.	$\frac{D_2}{D_1}$
Corrected Cohesiveness (PELEG, 1976)	Net work invested in the non-recoverable deformations of the first and second chews.	The ratio of the net work of the second cycle $B_1 - B_2$ divided by that of the first cycle $A_1 - A_2$.	$\frac{B_1 - B_2}{A_1 - A_2}$
Corrected Chewiness	The net energy required to chew a SOLID food to the point required for swallowing it.	The product of hardness, corrected cohesiveness and springiness index	$P_1 \times \left(\frac{B_1 - B_2}{A_1 - A_2}\right) \times \frac{D_2}{D_1}$
Resilience (PELEG, 1976)	Measurement of how a sample recovers from deformation in relation to speed and forces derived.	Resilience is the ratio of work returned by the sample as compressive strain is removed (known as recoverable work done A_2), to the work required for compression (known as hardness work done A_1).	$\frac{A_2}{A_1}$
Adhesiveness	The work necessary to overcome the attractive forces between the surface of the food and the surface of other materials with which the food comes into contact (e.g. tongue, teeth, palate). Work required to pull food away from a surface.	The negative area for the first bite, representing the work necessary to pull the compressing plunger away from the sample. (No adhesiveness is seen in graphs above.)	
Adhesive Force (Fiszman and Damaio, 2000)	The maximum force required to separate teeth after biting sample.	Maximum negative force generated during probe return.	
Gumminess Applies to semi-solid products only if they have no springiness & undergo permanent deformation	Energy required to disintegrate a SEMI-SOLID food product to a state ready for swallowing. Related to foods with low hardness levels.	The product of hardness and cohesiveness.	$P_1 \times \frac{B_1}{A_1}$
Cohesiveness A measurement of how well the structure of a product withstands compression	The strength of internal bonds making up the body of the product (greater the value the greater the cohesiveness)	The ratio of the work during compression (downward stroke only) of the second cycle B_1 divided by that of the first cycle A_1.	$\frac{B_1}{A_1}$
Chewiness Solid foods only	The energy required to chew a SOLID food to the point required for swallowing it.	The product of hardness, cohesiveness and springiness.	$P_1 \times \frac{B_1}{A_1} \times D_3$

Table 1: Table of sensory parameters used to characterize food items.

(Continued from p. 33)

springiness. Rest assured that food scientists have successfully used the various terms in Table 1 to characterize food items for years.

Packaging

Exploding QC interest in the use of texture analysis to certify the physical properties of food products coming out of the manufacturing process is now spilling over into related industries, like packaging materials for these same products. Texture analyzers, as explained above, are nothing more than simple instruments that compress or pull apart an item and measure the force and energy required to make it happen. They mimic the consumer who uses the sense of touch when evaluating a food item by hand or when popping the food item into the mouth and taking bites. Texture analyzers can also qualify the integrity of the packaging used to ensure that the food item survives transit from the manufacturing plant to the supermarket shelf to the end user who consumes the item.

Simple examples of tests on packaging materials include actions that consumers use everyday when opening items like yogurt containers with lids that must be peeled off. A peeling jig can be used with a texture analyzer to measure the adhesive strength needed to remove the lid from a sealed container. Tests like these are performed at different angles to simulate the approach taken by customers around the world. The preferred orientation for taking the lid off may be explained by the manufacturer in the information on the side of the container. Peel strength needed to open the container can be adjusted to accommodate the user group for which the product is intended, such as senior citizens and children.

Film materials are used extensively to package all kinds of food items. The ability of film to stretch without tearing is one of its important properties. A film support fixture makes it possible to evaluate the tear strength of the film. The texture probe has the shape of a punch that pushes down on the film sample, which is clamped in place during the test. The rate of travel for the probe can vary from 0.01millimeter (mm)/second to 10 mm/second and is usually selected according to the packaging process on which the film will be applied. R&D labs may conduct tests at different speeds to simulate multiple ways in which the film might be used. The test results not only qualify the film for use in packaging processes, but also provide guidelines for choosing films with specific tear strengths.

One of the more popular fixtures for general purpose testing using the tension mode is the dual grip assembly. This general-purpose device has two separate clamps that fasten the sample material and pull it apart. The bottom clamp is fixed to the base table while the top clamp attaches to the probe drive on the instrument. The top clamp moves upward at the start of the test and the instrument displays the measured force as the material stretches. The test objective is to measure the maximum force that a material can withstand when in tension mode.

A sliding friction test can also be performed on packaging materials in accordance with ASTM D1894. The objective is to measure how easily two materials slide over each other. The instrument measures the force needed to pull a weight robed in one material across the surface of a second material. The rate of travel for the weight is usually between 1 mm/second and 10 mm/second. When there is too much resistance between the materials, the friction may cause damage to one of the materials. This is an important test because it confirms, for example, that boxes of a specific food item, such as cereal packaged in a large container, will arrive at their destination with the printed information on the outside of the box in tact. Customers often judge a product by appearance on the shelf, so this test confirms that the surface of the package withstands the rigors of shipment.

The field of texture analysis has proliferated over recent years with the advent of many fixtures that can measure the firmness and robustness of packaging materials. The objective is to ensure survival of both the food item and its container from the production plant to the end user's kitchen, as well as to insure that the customer use of the item is optimized for ease and acceptability. ■

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BROOKFIELD ENGINEERING

The Thermo Scientific HAAKE Viscotester iQ.

Flow Behavior of Chocolate Melts: Working According to ICA Standards

An application note on viscotesters being used in QC applications for chocolate products

BY **KLAUS OLDÖRP, PHD**

The flow behavior of molten chocolate is a crucial parameter for many reasons. During production, the transport, filling, dipping, coating, and dosing steps depend on a well-defined viscosity and yield stress. Likewise, the properties of the final chocolate, like the look of its surface or its mouth feel, are directly related to the chocolate's viscous behavior.

Testing the viscosity is therefore one of the standard QC test methods for any company producing chocolate or using chocolate for their own production, e.g. chocolate-coated cookies.

There are various instruments available to make viscosity testing in QC easier and more reliable. For example, the Thermo Scientific HAAKE Viscotester iQ makes it is possible to use smaller measuring geometries, which reduces sample volume, time for temperature equilibration, and cleaning effort. Also, smaller shear rates are accessible due to the improved sensitivity, which enhances the reliability of yield stress calculations with extrapolation methods like the Casson model.

A Look at a Preparation Method

Two chocolate samples, a milk chocolate and a dark chocolate, have been prepared according to ICA method 46 by putting chocolate pieces into glass containers, sealing the containers and leaving them in an oven at 52 degrees Celsius for between 45 and 60 minutes. Meanwhile, the cup and bob of the measuring geometry are preheated to 40 degrees Celsius in the Peltier temperature control unit of the Viscotester iQ.

For the tests done for this report, the CC25 DIN Ti measuring geometry has been selected. This small cylindrical system with only 16.1 milliliter sample volume fits into the Peltier cylinder temperature control.

The ICA test method 46 has been translated into a Thermo Scientific HAAKE RheoWin job. The shear rate profile is shown in Figure 1.

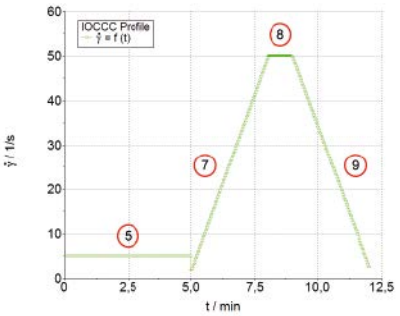

Figure 1: Shear rate profile applied according to ICA method 46.

HAAKE RheoWin Job consists of three parts: sample conditioning, testing, and evaluation. The sample conditioning should always be part of the test method itself to ensure that it is not forgotten and always performed in the same way, which improves the reproducibility of the results. During the conditioning part the sample is kept at rest with the cylindrical upper part of the measuring geometry already in measuring position. During this time any mechanical stress caused by sample loading and closing the geometry should relax completely while at the same time, the whole sample should reach the temperature the test is going to be performed at.

In the final part, the data evaluation is performed automatically by HAAKE RheoWin. To calculate the yield stress of a chocolate melt, the traditional Casson model and the modern Windhab model can be selected from a long list of fit models. In a more simple approach, "Determination of Chocolate Viscosity" published in *Journal of Texture Studies* suggested to use the shear stress value at 5 1/s as the yield stress. If this method is preferred, a simple interpolation calculation in HAAKE RheoWin will do the job.

In addition, a steady-state viscosity curve at 40 degrees Celsius has been recorded for both samples. Compared to transient viscosity data from shear rate ramps, the steady-state viscosity is independent from time-dependent effect and the slope of the shear rate ramp. For comparison of viscosity data, the steady-state viscosity is the best choice because it is independent of the instrument used and can be directly correlated with the shear rate applied.

The Results

A typical representation of the results from a test according to ICA method 46 is shown in Figure 2 on page 36. The red curves depict the viscosity and the blue curves the shear stress. It clearly shows that the milk chocolate has the higher viscosity by a factor of two or more.

The viscosity curves for the increasing shear rate ramp and the decreasing shear rate ramp are almost identical for the dark chocolate. In contrast, the milk chocolate shows a pronounced thixotropic behavior with significant differences between the two viscosity curves.

Green parabolic curves extrapolating the flow curves to a shear rate of 0 1/s represent the Casson fit. The vertical green lines indicate where the interpolation according to Servais has been calculated. Results of

(Continued on p. 36)

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the different methods to determine the yield stress of the two chocolate melts have been summarized in Table 1.

The first and probably most important result from Table 1 is the insight that even from the same data, different models give different results. Therefore, only yield stress values calculate with the same mathematical model can be compared.

Independent of the model chosen, the milk chocolate in this example shows the higher yield stress, the higher viscosity, and the stronger thixotropy.

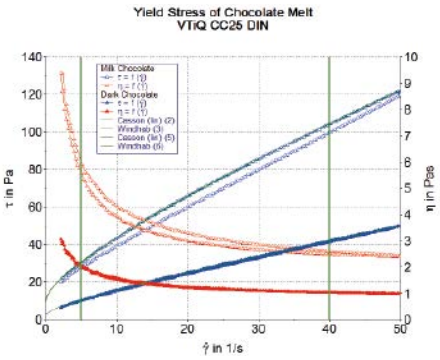

Figure 2: Test results for a milk chocolate (open symbols) and a dark chocolate (filled symbols). The milk chocolate shows higher viscosity values (red curves), stronger thixotropy, and a higher yield stress. The extrapolation of flow curves (blue curves) to 0 1/s has been calculated according to Casson. The green vertical line at 5 1/s represents yield stress according to Servais.

Table 1: Determination of yield stress based on the data from Figure 2 using different models.

	Milk Chocolate	Dark Chocolate
τ_0 Casson / Pa	8.9	2.1
τ_0 Windhab / Pa	14.7	4.0
τ_0 Servais et al./ Pa	30.0	10.4

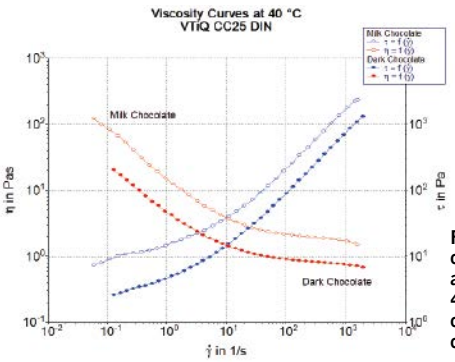

Figure 3: Viscosity curves of milk chocolate and dark chocolate at 40° C. The milk chocolate shows a significantly higher viscosity.

Summary

In QC, the rheological characterization of chocolate mainly focuses on its viscosity and yield stress. Using an instrument that combines sensitivity and strength, like the HAAKE Viscotester iQ, can help to successfully test chocolate melts over a wide range of shear rates. The commonly accepted test method according to ICA method 46 can easily be performed using only a small sample. The same is true for steady-state viscosity curves. ■

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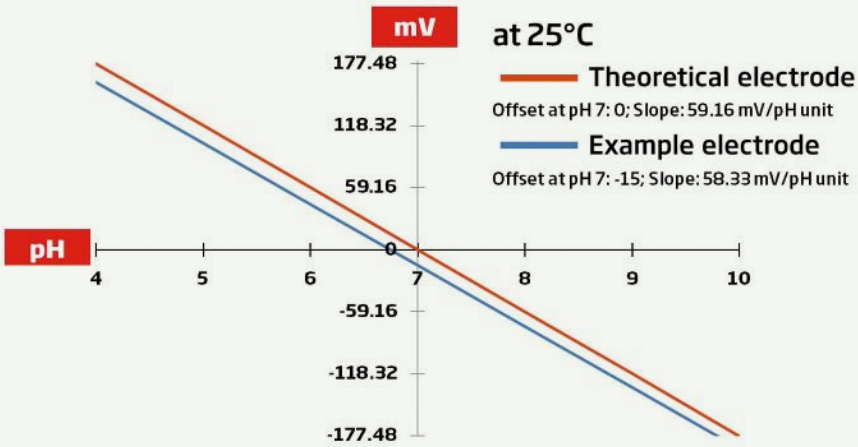
REFERENCES FURNISHED UPON REQUEST

Determining pH During Cheesemaking

Guidelines and considerations for measuring pH in dairy products

BY **DAVID MASULLI**



Sample Calculation:
pH electrode generated -15 mV in pH 7.01 buffer and +160 mV in pH 4.01 buffer
160 mV – (-15mV) = 175 mV
175 mV / 3 pH units = 58.33 mV/ pH unit
(58.33 / 59.16) x 100 = 98.6% slope

Measurement of pH presents a critical QC step in the production of dairy products. The pH offers an indication of contamination from bacteria or chemicals while also providing a convenient method to estimate the acid development of a dairy product. As there are a myriad of different sampling methods, electrode care guidelines, and electrode designs, determining best practices for pH measurement can be a challenge. This guide will discuss electrode design, maintenance, and practices for measuring the pH of dairy products. While the focus is on cheese, the guidelines can be applied to a much broader range of dairy products.

Cheese is a versatile food that is valued worldwide for its high nutritional value and long shelf life. There are hundreds of cheese varieties, all prepared with differing compositions and techniques. Due to this variance and complexity in production, cheese is the most diverse form of dairy product. The cheesemaking process involves multiple pH quality control steps to ensure the desired flavor is achieved and batches remain consistent.

Calibration

Prior to measurement, pH meters must be calibrated. Calibration adjusts how pH values are assigned to incoming millivolt (mV) readings from the electrode. The pH electrodes generate a mV potential based on hydrogen ion activity; this activity is determined by pH glass, which is specially formulated to measure the hydrogen ion. Hydrogen ions contribute to how acidic a sample is, while hydroxide ions contribute to how basic a sample is. The pH scale ranges from 0 to 14, with pH values less than 7 being acidic, pH values greater than 7 being basic, and pH 7 being neutral. As pH glass breaks down and changes over time due to normal wear and tear, calibration of the meter corrects for these changes in the glass; the quality and frequency of calibration procedures will ultimately determine the accuracy of data. For best results, calibrate the pH meter at least once per day with standards that bracket the expected pH range of the samples. Because cheese typically has a pH value between pH 5.0 and 6.7, ideal calibration standards are pH 4.01 and 7.01; a third buffer may be incorporated for higher precision.

The theoretical relationship between pH and mV is defined by the Nernst equation. Based on this equation, a theoretical electrode will read 0 mV in pH 7.0 buffer (the value of which is known as the offset), and will have a slope of -59.16 mV per change in pH unit. Calibration corrects for deviations of electrode behavior from this theoretical relationship, but can only correct for so much before the accuracy of the measurement is affected. Many meters will have indications of electrode condition or slope condition, but it is recommended to use the mV mode on a pH meter to periodically check electrode offset and slope. To perform an electrode offset and slope check, first measure and record the mV value in pH 7.0 buffer; this is the electrode offset. Next, measure the mV value of a second buffer, such as pH 4.0. To determine the electrode slope, calculate the difference in mV between the two buffers and then divide this by the number of pH units between buffers. To convert this to electrode slope percentage, divide the electrode slope by the theoretical slope of 59.16, and multiply by 100. Acceptable ranges for offset is ±30 mV and slope percentage is 85 percent to 105 percent; anything outside of these ranges may result in inaccurate measurement.

Production

Before cheesemaking begins, milk must be tested for quality. Milk is slightly acidic, typically in the range of pH 6.5 to 6.7, due to the presence of phosphate, citrate, and other buffering salts present. Values

(Continued on p. 38)

(Continued from p. 37)

above this range may suggest illness in the cow; values below this range may indicate that lactic acid fermentation has begun. Although lactic acid fermentation is commonly performed as part of the cheesemaking process, it is undesirable in the raw milk because potentially pathogenic bacteria, rather than the starter cultures, are performing the fermentation.

The production of cheese begins with the metabolism of milk by microbial cultures. These cultures ferment the milk under controlled conditions, producing lactic acid from the sugars that are naturally present. Fermentation causes a decrease in pH and allows for flavors to develop. Next, the milk is separated into solid and liquid components through the use of rennet, an enzyme complex that is responsible for the curdling of proteins in milk. The resulting solid component is known as curd while the liquid component is called whey. Once the milk is coagulated, the curd is fermented until it reaches a pH of 6.4. It is subsequently separated from the whey and left to form into a mat. At this point, the mat is cut into sections and layered to expel more liquid. Fermentation continues in this layered form until the pH reaches pH 5.1 to 5.5 and is then salted or brined. Additional treatment may be performed based on the desired style of the cheese before the product is stored, aged, and packaged.

It is best practice to measure pH frequently throughout the cheesemaking process from raw milk to finished product, as pH influences the microbial community that contributes to flavor and texture development. If pH during cheese processing is too low, the cheese may be prone to a brittle or pasty texture, and can potentially harbor the growth of mold after packaging. If pH is too high, the cheese may become too firm, and can be dangerous for consumption due to risk of pathogen formation.

When pH is measured in dairy products, electrode fouling is a common challenge. Electrode fouling occurs when fats and proteins obstruct the reference junction or attach themselves to the sensing glass of the electrode.

Electrode fouling can be minimized with proper maintenance, storage, and cleaning. Buildup on the sensing glass causes inaccurate and sluggish measurements, as it directly affects the glass' impedance. An offset outside of the acceptable range of ±30 mV usually indicates the pH glass bulb is dirty or coated. Cleaning solutions are effective at both disinfecting and removing oil and protein deposits. It is also recommended to store electrodes in storage solution when not in use. This ensures that the sensing glass stays hydrated and ready for measurement.

The Design

Conventional pH electrodes have a ceramic frit reference junction that allows the internal reference electrolyte to come into contact with the sample. In dairy products such as milk and cheese, proteins and other colloidal solids can partially or completely clog this ceramic frit, resulting in slow electrode response or inability to take a reading. For dairy, it is recommended to purchase a pH electrode with an open junction rather than the traditional single ceramic junction. The open junction design utilizes a gel reference electrolyte that comes in direct contact with the sample; because there is no physical junction, clogging is no longer a potential issue. The open design also offers an added benefit of a faster response time due to a higher flow rate of electrolyte into the sample. Other types of electrode junctions exist, including PTFE junctions, triple ceramic frit junctions, and ground glass junctions; these designs confer their own advantages, but are more suited for other applications.

Conventional pH electrodes have a spherical sensing bulb that provides an increased surface area for the sample to interact with the sensing glass; this bulb shape is ideal for measurement in aqueous solutions. However, other tip designs exist on the market, and each shape offers an advantage in certain applications. For example, conical tipped pH electrodes are pointed so that they may easily penetrate semisolid objects, such as cheeses.

If measuring the pH of cheese with an electrode constructed of a spherical bulb and ceramic reference junction, a homogenized slurry of cheese and deionized water must be prepared. A slurry is necessary because the flow rate of electrolyte into a solid or semisolid cheese alone is too slow to enable a direct measurement. An electrode utilizing a conical tip shape in combination with an open reference junction allows for direct measurements of cheese samples, thus saving on preparation time and eliminating a potential source of error. Conversely, for other dairy products such as milk or cream, the spherical tip may be more suitable due to its wider area of contact that permits a faster stabilization time. Ultimately, selection of the tip should be based on the nature of the sample matrix.

Temperatures

A wide temperature range is covered in the cheesemaking process; pH measurements may be taken in refrigerated conditions or conditions as hot as 85 degrees Celsius, which is seen in the production of ricotta. This presents a measurement challenge since hydrogen ion activity, and therefore pH, changes based on temperature. Temperature compensation allows measurements at high and low temperatures by comparing the measured pH to a reference temperature. Automatic temperature compensation is available on most pH meters so users do not have to consider their temperatures during measurement.

Temperature also changes the behavior of the pH sensing glass. As temperature increases, the impedance of the glass decreases, and vice versa. This relation means that while a reading may stabilize more quickly at higher temperatures, the glass degrades at a faster rate. Conversely, readings may take a long time to stabilize under low temperatures due to the higher impedance. Manufacturers minimize these measurement difficulties by producing different glass formulations specifically designed for high or low temperatures. In short, if measurements must occur in both hot and cold samples it may be desirable to have an electrode dedicated for each of these extremes. However, if measurements are normally taken under standard conditions and only rarely under extreme conditions, it may be best to perform measurements with a general-purpose electrode.

Details for when and where to monitor pH can change depending on specific product, but in all cases, proper electrode care and design selection is key for reliability of measurement. When implemented properly, pH measurements can ensure safe, consistent, and quality products. ■

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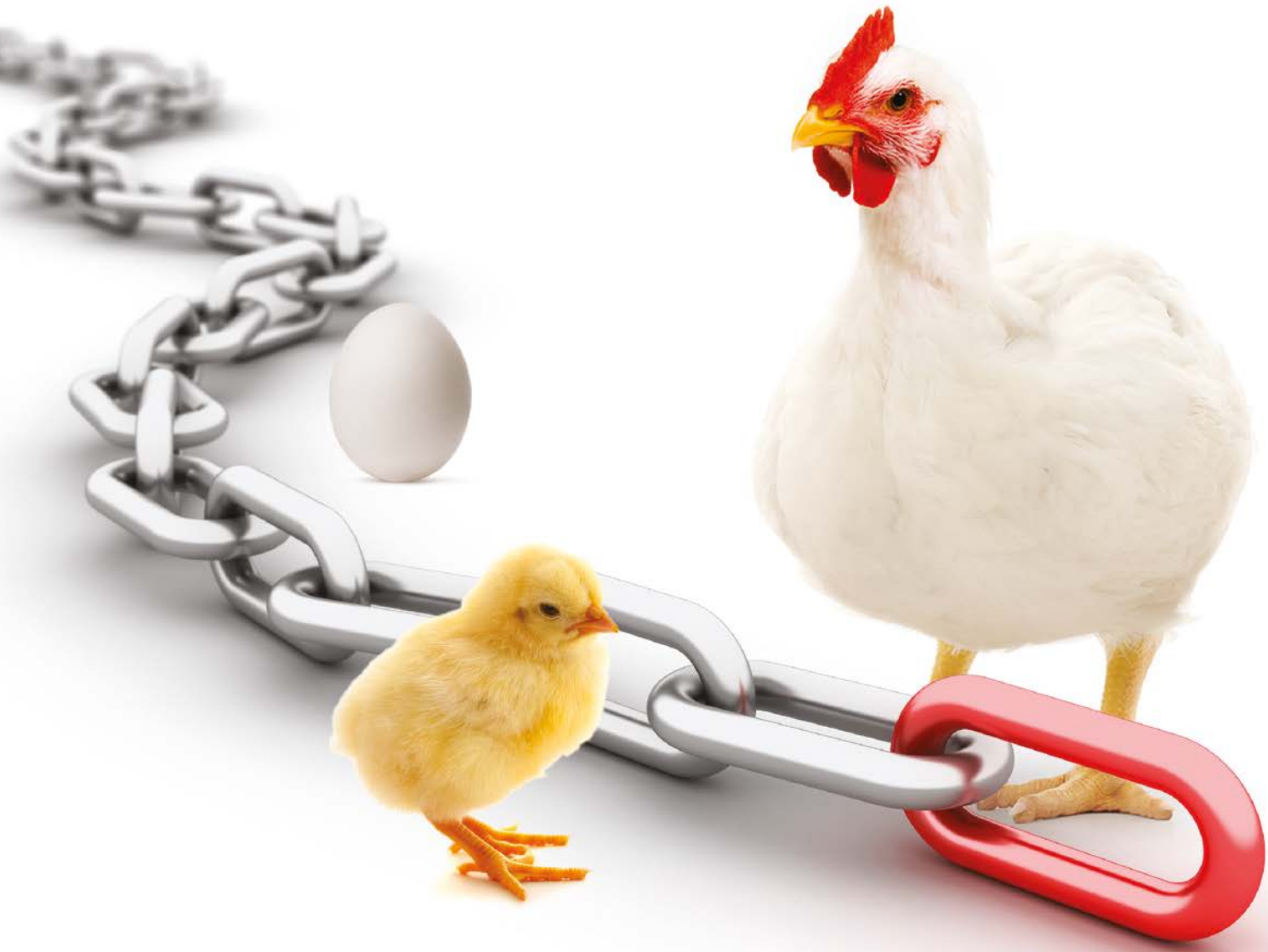

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Keep Your Cool

Automation technology played a critical role in Hill Country Bakery's implementation of a temperature monitoring system at its distribution center

BY **GEORGIA H. WHALEN** AND **NICK HITCHCOCK, PE**

At Hill Country Bakery, production processes and monitoring is a major priority to ensure product quality. The company is proactive in investing in technology and automation to meet its quality goals. Hill Country Bakery's commitment to producing the highest quality baked goods has earned the company its coveted SQF2000 level 2 Certification.

Achieving Safe Quality Food (SQF) Level 2 Certification requires establishment of a Hazardous Analysis and Critical Control Points (HACCP) food safety plan that is benchmarked by the Global Food Safety Initiative (GFSI). Preventing potential problems from occurring is the paramount goal underlying a solid HACCP plan. Companies reaching this level of certification must pass SQF audits and continuously show improvement of rigorous and credible food safety management systems.

A key part of every successful food manufacturer's safety program involves refrigeration of ingredients and finished products. Temperatures need to be monitored and kept within a narrow range to ensure product quality and safety. Hill Country Bakery was not satisfied with its temperature monitoring system for its 55,000 square foot cold storage distribution center located in San Antonio, Texas for a number of reasons.

The distribution center stores both ingredients for manufacturing and finished products for distribution to retailers and food service distributors. The bakery relies on temperature monitoring and logs to ensure the highest standard of product quality for customers and to meet SQF monitoring and reporting requirements.

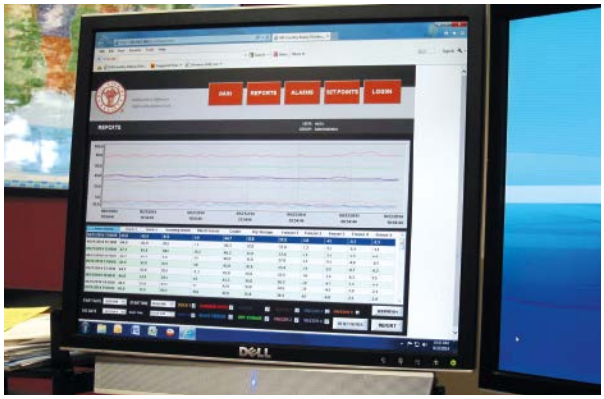
The distribution center had multiple refrigeration zones with hard-wired temperature probes to collect and monitor temperature data. The problem was the connecting wires were prone to damage by forklift trucks which could temporarily interrupt the continuous collection of data. In addition, the method for data collection was inefficient, temperature readings had to be manually logged into a database for reporting; a time consuming task with inherent risk of human error.

Hill Country Bakery hired Patti Engineering to assist with the engineering, design, and implementation of a more advanced and automated temperature monitoring system. "We had a huge gap that needed to be filled before our SQF level 2 audit. The continual degradation of our previous monitoring system continued to put us in a bind. There were gaps in data as well as no tracking of corrective actions in the event that a temperature issue was found," explains Nick Rendon, maintenance manager for Hill Country Bakery. "We approached Patti Engineering with our desires for a reliable system as well as a system to resolve some of the issues that we had seen with the antiquated system. Their solution was a cost effective, reliable, wireless solution that would address all our needs and satisfy the requirements for SQF. They worked expeditiously to successfully delivery our system in time for our audit."

Patti Engineering's solution included elimination of hard-wired temperature sensors, and the addition of a powerful supervisory control and data acquisition (SCADA) for automated data collection and real-time monitoring. The ability for remote monitoring and alarm notification via mobile devices such as smartphones completed the plan for improvements.

Freshloc wireless temperature sensors were provided by Patti Engineering to eliminate the recurring problems associated with damage prone hard-wired sensors. InduSoft Web Studio was chosen for development of the human machine interface and SCADA because of its open platform, large library of drivers, and flexibility for customization.

Patti Engineering's team customized Indusoft Web Studio to meet Hill Country Bakery's specific needs. Real-time monitoring of all temperature zones can now be viewed from the SCADA at the plant or



PATTI ENGINEERING

Temperature history report screen from SCADA system.

remotely on a mobile device. Immediate notifications of alarms are sent via email when a temperature issue arises to prevent compromised quality and/or safety problems. Manually generated logs were eliminated. All data collection for temperature zones and alarms are automated and recorded into an SQL database. Temperature and alarm reports can be generated from this database quickly and easily for any specified period of time.

In addition, Patti Engineering programmed the Indusoft software to communicate directly to the gateway of the temperature probes via ModbusTCP, allowing the engineers to cut out any programmable logic controllers or other control between the sensors and SCADA system. This saved Hill Country Bakery hardware cost and engineering development time for the project.

With the new temperature monitoring system completed, Hill Country Bakery can easily generate reports for quality assurance to customers and quality compliance for audits. Data integrity is improved thanks to the automated recording functions and moving through the auditing process is much faster than before. A cost savings benefit has also been realized with the automated data collection with the reduction in the excessive amounts of hours that employees spent logging data by hand.

The flexibility of InduSoft Web Studio will allow Hill Country Bakery to add functionality in the future, such as the ability to not only remotely monitor temperatures, but to actually control/adjust temperature settings. Another option is to add data collection from the manufacturing lines to monitor and improve overall equipment effectiveness. ■

Whalen is director of marketing for Patti Engineering, a certified member of the Control System Integrators Association (CSIA), a global non-profit professional association that seeks to advance the industry of control system integration. Reach her at gwhalen@pattieng.com. **Hitchcock** is a senior engineer for Patti Engineering.


KLÜBER LUBRICATION

Food-Grade Lubrication

Utilizing single point automatic lubricators can increase both productivity and safety in the food industry

BY **TOBY PORTER**

When it comes to enhancements in food safety from a lubricant perspective, previously unknown terms such as NSF H1 and CFIA have become common place. Now, food industry professionals have a myriad of options when choosing products that help achieve targeted levels of food safety for their facility. Even ISO 21469, which refers to the hygienic manufacturing process for a food-grade lubricant, is becoming well known throughout the industry. It accounts for the lubricant and its ingredients, as well as the manufacturing process, handling, packaging, and storage. The goal of this holistic approach is to ensure the lubricant is not only manufactured in accordance with the standards, but that it is also delivered intact and free from outside contaminants.

One aspect of these programs that is often overlooked is the application of food-grade and ISO 21469 certified lubricants once the grease cartridge and/or oil pail is inside a facility. One option to consider is the use of a single point automatic lubricator (SPAL). A SPAL delivers the correct amount of lubricant at the appropriate interval over the lifetime of the applicator. When combined with the optimum lubricant, this can reduce the operating temperature of a component and avoid other issues that can occur due to under-lubrication. By enabling best-practice preventative maintenance routines, it eliminates much of the hassle of planning and scheduling manual lubrication, helping to reduce labor and enhance plant safety. It is important to understand the benefits that can come from a SPAL, not only from a maintenance and safety standpoint, but also from a quality and reliability standpoint.

Maintenance

The use of a SPAL can lead to increased uptime for machinery by offering continuous, uninterrupted lubrication for various components. These units can work to avoid common issues, such as cross-contamination with incompatible materials, ingress of water into a lubrication point, missed or over-lubrication of key components, excessive downtime for maintenance, and increased labor costs from manual lubrication.

These issues can significantly impact the bottom line by reducing productivity and can also lead to unexpected and/or premature machinery failures.


KLÜBER LUBRICATION

Quality

R&D within the lubricant industry has advanced in recent years. Products available today now cover applications that were thought to be possible only from non-H1 materials. Many organizations are now realizing it is not just about the decision to go to a food-grade program, but to ensure that the application of these products is done in a controlled manner. Using a SPAL can help improve food safety by avoiding improper mixing with non-food-grade materials and contamination coming from an open system and/or lubricant container.

With these units, quality managers can be confident that the NSF H1 (food-grade) lubricant is being used in the location identified as a potential food contamination risk.

A number of SPALs are available in the marketplace, but it is important to understand that the proper lubricants are being used to handle a specific application while also providing adequate food safety properties. It's equally as important to ensure the lubricants are being applied in a manner that continues along the food safety path in which they were manufactured. This is where the use of a SPAL can become vital to maintenance and quality programs. For example, one system can provide grease from one reservoir to multiple bearings—another can deliver oil from one tank that can feed different drip nozzles for a baking oven chain. SPALs may be recommended to provide a slow but continuous and defined volume of lubricant to an application point to minimize outside contamination.

The use of a SPAL combined with NSF ISO 21469-certified lubricants ensure the holistic approach to quality and safety has been continued beyond the production walls of the manufacturer and straight through to the application point of a component. ■

Porter is the food market manager at Klüber Lubrication North America L.P. Reach him at toby.porter@us.kluber.com.

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Floor Cleaning Eye-Opener

Advanced cleaning techniques on soiled floors can eliminate the direct/indirect contact areas that are sources of contamination

BY **ROBERT KRAVITZ**

Perhaps it's time to let food service facility managers, operators, and quality control professionals in on a little secret: Mops spread soils which can make floors slippery, unhealthy, and dangerous but properly cleaned floors improve traction, health, and safety.

Cleaning workers and others in the professional cleaning industry have either known or suspected this for decades, but it does not appear that the word has spread up to the C-suite regarding mops. And, if the ultimate goal of professional cleaning is to protect human health, then this little secret can have serious ramifications for all types of facilities, including those in food service.

The use of mops is still prevalent in restaurant cleaning. In fact, in many facilities, including hospitals, schools, hotels, and restaurants, mops and mop buckets are as commonly used as vacuum cleaners, sprayers, and cleaning cloths.

In all fairness, mops are recommended for certain tasks in a food service facility. They are perfect for cleaning up spills or moisture buildup at building entries, both to help prevent a slip-and-fall accident in kitchen areas. But, it is the ongoing use of mops and the cleaning solution in the mop bucket that can potentially cause serious contamination and health risks for food service facilities. This was first made clear in a hospital sanitation study published in *Applied Microbiology* in 1971. While it was conducted in a hospital setting, the findings can and do apply to any commercial facility, including food service.

The researchers wanted to find out if germs and bacteria that may cause disease can be spread through cleaning. Of central concern were all the tools customarily used to "wet-mop" or clean floors: mops, buckets, and the cleaning solution. Here is what they reported:

Following the demonstration of massive spread of bacterial contamination throughout the hospital by the wet-mopping techniques in use, quantitative studies were undertaken to determine the source of contamination and to institute measures of control. It was found that mops, stored wet, supported bacterial growth to very high levels and could not be adequately decontaminated by chemical disinfection. Laundering and adequate drying provided effective decontamination, but build-up of bacterial counts occurred if mops were not changed daily or if disinfectant was omitted from the wash-water.

In other words, as soon as the mop is used, literally from its first application, it becomes soiled and contaminated. This builds up over time and as it does, the cleaning solution also becomes contaminated. The study did note that the use of a disinfectant can help prevent this. However, as the mop, bucket, and cleaning solution become more and more soiled, what is referred to as the efficacy of the disinfectant—its ability to kill germs and bacteria—begins to diminish. As this happens, the mop begins to spread soils and potentially harmful contaminants.

Before exploring this topic further, a fair question to ask is why is it so important to keep floors hygienically clean? The reason is actually quite simple. We have many more contacts with floors than most people realize. According to Mark Warner, formerly with the U.S. Department of Homeland Security, we have as many as 50 direct and indirect contacts with floors *everyday*. Every time we tie a shoelace, as an example, that has also touched a floor, we have come in indirect contact with the floor. And, if that floor is contaminated—as is often the case during the course of the day—cross-contamination is possible.

This was the key concern in the hospital study discussed earlier and the issues they encountered are reasons why the

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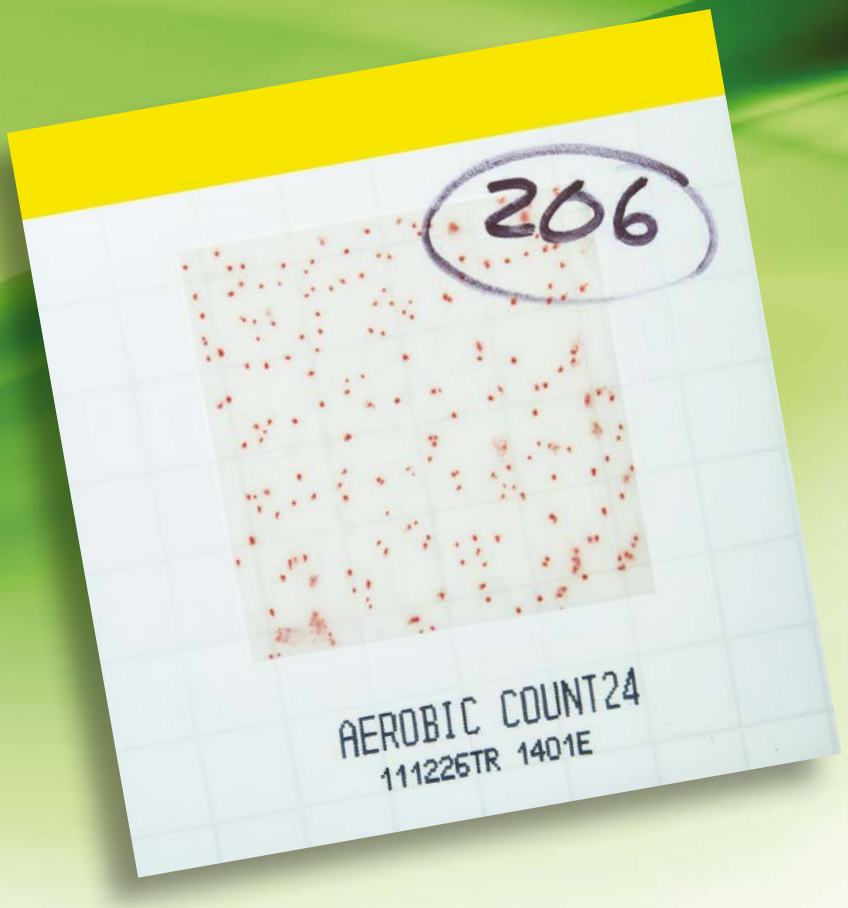

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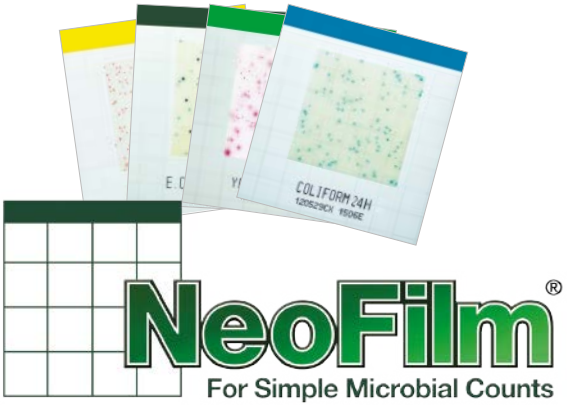

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(Continued from p. 44)

food service industry should prioritize addressing these risks. Later, we will discuss how food service managers can address this problem.

Other Cleaning Culprits

While the "wet mopping" process is probably highest on the list of cleaning tasks that can spread soils, germs, and bacteria, instead of remove them, mops and buckets are not the only culprits. Another key culprit is cleaning cloths, whether traditional terry cloth, which is often found in food service operations, or microfiber. Soils and microorganisms build up on them as they are used and eventually can move from one surface to another, potentially spreading harmful germs and bacteria.

For instance, it is not uncommon for custodial workers to clean restroom fixtures with a cleaning cloth that is then used to clean high-touch (frequently and commonly touched) areas, such as light switches, door handles, ledges, railings, etc. One very simple way food service managers can prevent this is to incorporate a color-coding system. A typical color-coded program for cleaning cloths looks something like this:

- Red: restrooms and restroom fixtures,
- Blue: kitchen area surfaces, counters, etc.,
- Yellow: high-touch areas, and
- Green: office desks, office equipment, chairs, office counters, etc.

Taking this a step further, some facilities now use what are termed "smart towels." "Smart" because not only can they be used in a color-coded cleaning system, but they can also be folded into numbered quadrants. For instance, if sections 1, 2, and 3 have been used, the cleaning worker can fold the towel to quadrant 4, using a clean piece of the towel for each new cleaning task.

Making Floors Hygienically Clean

While it is relatively easy to prevent the spread of contaminants using cleaning cloths, it gets a bit more complicated when it comes to floor cleaning. However, there are ways and means possible.

One option is the use of a new generation of steam vapor machines. These systems heat water to 240 degrees Fahrenheit or higher, which is then pressurized to about 60 pounds of pressure per square inch (psi). The steam vapor can be used to clean floors, surfaces, restroom fixtures, and other areas. And, according to Benjamin Tanner, PhD in microbiology and immunology from the University of Arizona, steam vapor provides "a nontoxic, environmentally friendly way to both clean and disinfect at the same time."

KAIVAC

In a commercial kitchen, steam vapor can be an excellent tool because it melts away grease and oil. However, the key drawbacks with steam vapor cleaning are that it can be a rather slow process and, when used on floors, it may require damp mopping after use to remove residue from the floor. Because our goal is to not use mops, this can be a problem. Further, considerable care must be taken when using steam vapor machines due to the very high heat generated.

There are also different types of hard surface equipment—some use a combination of steam or very hot, pressurized water. Advanced equipment features a vacuum system to recover cleaning solution as the machine is used, while others use a squeegee to move chemicals into a floor drain. Unfortunately, this squeegee process can be problematic because it can spread contaminants from one area to another when performed.

Another option is to use what the International Sanitary Supply Association (ISSA), the worldwide cleaning association, refers to as spray-and-vac or no-touch cleaning systems. These systems inject chemicals onto the floor or surfaces being cleaned. Allowing for a few minutes of dwell time—enough time for the chemicals to effectively loosen and suspend soils—the same areas are then high pressure rinsed. The final step is vacuuming the just cleaned areas with the machine's built-in wet vac system. While the process seems like it may be time consuming, ISSA reports in its book, *540 Cleaning Times*, spray-and-vac systems can be as much as two-thirds faster than traditional cleaning methods, whether used to clean floors or restroom fixtures.

Testing for Results

The use of adenosine triphosphate (ATP) monitoring systems is certainly not new to the commercial food service industry. However, in most commercial kitchens, they are used to test cooking surfaces, tools, and equipment. As we know, while these devices do not indicate specifically that germs and contaminants are present on a surface, a high ATP count can serve as a warning that this might be the case.

Since we now know that soiled, contaminated floors have the potential to spread disease, it is wise for food service managers to also begin using ATP monitors to evaluate their floors. A good practice is to test the floor before cleaning and then after cleaning. This can evaluate the effectiveness of the cleaning process used and if you are still using mops and buckets, conducting an ATP test after cleaning may prove to be a real eye-opener.

Kravitz is a frequent writer for the professional cleaning and building industries. Reach him at Robert@alturasolutions.com.

Trailblazer Foods audits local strawberry farm.

Supporting a Store Brand

A manufacturer's perspective on the fundamentals of choosing quality suppliers

BY **TOM BOYD** AND **JIM JACKSON**

Private labels have given retailers a chance to create new profit centers, but they've also introduced a number of risks, including those associated with product recalls due to safety or quality issues. To minimize risks, it's important for retailers and product purchasers to partner with manufacturers who can demonstrate a commitment to food quality and food safety. In addition, buyers will need to find manufacturers who can deliver the goods in terms of meeting specific needs as well as pricing limitations.

Staying Power of Store Brands

What was once thought to be a fad appears to be here to stay. Private labels have been around for some time, but they really began to find favor during the Great Recession. Consumers, perhaps even begrudgingly, turned to store brands to stretch their limited dollars. In doing so, many shoppers discovered that high quality products could be had at a lower cost than national brands, which often need to bump up prices to cover their costs of marketing and shelf space.

While broad economic hardship has seemingly passed, the growth of private label continues. According to the Private Label Manufacturers Association's *2014 Annual Private Label Yearbook*, unit and dollar shares rose in grocery stores. Since 2011, store brands in supermarkets have gained three percent on an annual basis, and across the board, private labels across all outlets have grown five percent annually.

What's more, a relatively young segment of the population has adopted store brands. Consumer research by Mintel shows that 63 percent of Millennials and post-Millennials are high users of store brands, with Generation X reporting the second-highest level at 55 percent. Retailers now have an opportunity to build loyalty that, in turn, has potential to supply regular sales and profits far down the road.

Providing consumers with a high quality product that rivals that of a national brand—at a cost savings—is certainly one of the best ways to start building loyalty. But quality doesn't end with the taste, texture, or packaging of a product. Safety is of paramount importance. Product recalls cost companies significant time, money, and effort to execute, and the economic impact to the U.S. alone was found in one 2010 study to be $152 billion.

Given the many players in the production chain today, how can retailers and product purchasers assure the quality and safety of a food item?

Get to the Source

Being selective about production partners—from growers to processors and manufacturers—is critical. For products that rely on fresh produce from farm fields and orchards, it's necessary to develop a clear understanding of the conditions under which ingredients are grown and otherwise produced in order to minimize risks of food safety hazards and assure the highest quality of final product.

Manufacturers and co-packers have a vested interest in a retailer's process: Their own success depends on the reliability of their suppliers. Work with manufacturers that provide transparency into their methods for sourcing ingredients. They should maintain strict criteria for considering a source as well as documentation supporting the selection of a source.

A supplier compliance procedure should be rigorous. For example, Trailblazer Foods, which produces store brand as well as proprietary items, carries out regular, in-person supplier audits that involve touring a current or potential supplier's operations in order to ensure that its selected ingredients meet strict food safety and quality requirements.

Audits provide an up-close view of a supplier to assess for best agricultural practices and verify that ingredients are produced, packed, handled, and stored in the safest manner possible. When timed well, visits may coincide with harvest, at which point the company can observe the care with which fruit is gathered and whether it's being picked at its peak for the best flavor.

In addition, an audit provides the opportunity to verify that proper pre-requisite programs are in place to support a supplier's Hazard Analysis and Critical Control Points (HACCP) plan. Numerous programs are up for review, such as pest control, sanitation, maintenance, waste management,

(Continued on p. 48)

TRAILBLAZER FOODS

(Continued from p. 47)
recall and withdrawal, and Good Manufacturing Practices.

Just as important as dedication to creating a quality product is a sense of pride in operations. Visiting a site provides the chance to speak with key personnel. Not only does engaging in dialog offer insight to the product but it indicates whether attitudes are positive and that there is a true desire to be a part of a larger team.

Finally, the atmosphere and care on a farm must extend beyond the fields and on the road to the processing plants. Farms must put thought into logistics for transporting their fruit, ensuring that product is handled appropriately and kept at proper temperatures. Plans should be well thought out and economical.

Adhere to Stringent Examinations

With private label products, retailers risk their reputations on the quality contained within. And it's not just quality that is a concern. Food safety is critical, and many retailers with their own labels are requiring certifications from all members within their supply and manufacturing chains.

In the last five years, for instance, several national grocers began to require all of their suppliers adhere to Global Food Safety Initiative (GFSI) standards. Meeting such standards provides a "high degree of confidence" in the design, implementation, and maintenance of food safety management systems. After fully and consistently implementing the requirement across all private label suppliers, the retailers are seeing a significant decrease in the number of recalls.

When selecting a manufacturing partner, develop an evaluation process that incorporates a review of documents and certifications. Such a step ensures that suppliers will be in line with a retailer's commitment to providing quality, safe food products. As there is no overarching, governing body that certifies vendors and suppliers, it's up to retailers and their manufacturing partners to establish guidelines for those interested in doing business with them.

For processors and manufacturers, GFSI standards are common and provide assurance of safe food management programs. In addition, the Safe Quality Food (SQF) certification program is recognized worldwide among those seeking a "rigorous, credible food safety management system." With the recent passage of the Food Safety Modernization Act, all parties in the food supply chain will be required to pay heed to additional food defense measures.

When evaluating along the supply chain and assessing farms, consider Good Agricultural Practices (GAP). Following GAP may involve delving into farm sanitation or spray records. In essence, by taking the time to verify production, handling, packaging, and storage practices, the farm's ability to produce safe, quality food will become evident.

During the evaluation process and facility or farm tours, request supporting documentation of an operation's commitment to safety and quality. Documents may include policies, procedures, a HACCP plan, audit schemes, and results, as well as any pertinent certifications. Be sure documents are up-to-date, and be prepared to invest significant time in researching a potential supplier or vendor. Depending on the supplier, the produce, and any unique parameters for ingredients or handling, the process could take anywhere from several days to a couple of months.

A supplier evaluation program does not end with the initial approval. Rather, each supplier should be evaluated continuously to ensure that standards are maintained. Consider requiring annual updates of audit records and certifications. Also, revisit farms and facilities several times a season for greater assurance that safe, quality ingredients are received.

Price Drives Decisions

Price is a critical factor in any arrangement, but it is typically considered last in a three-tiered deal. Once suppliers are vetted for the volume of product required and quality standards are met, price must fit into a company's model.

For private labels, price can be a sensitive issue. National brands tend to set pricing, and private labels typically sell at a 25 percent to 30 percent discount. If farmers are facing a difficult year, costs may be driven up. Retailers may need to accept reduced margins, consider offering their consumers less of a discount relative to major brands, or find a cheaper source for their ingredients.

To secure greater flexibility in pricing and availability, consider developing a stable of suppliers for any given commodity. If one is unable to fulfill a contracted amount, another may be able to make up the balance. Most processors allow for multiple suppliers, ensuring a higher assurance that end demand can be met.

Stay on Top of Special Requests

Consumers are increasingly seeking out foods with specific qualities: certified organic, kosher, vegan, and gluten-free are just a few of the overriding buzzwords on grocer's shelves. For some consumers, their selections have a real impact on their overall health and well-being, so it is critical to find vendors and suppliers with reliable and traceable sources. Maintain any relevant certifications, in addition to those for food safety, to provide customers with documentation if requested.

Traceability is an essential part of the manufacturing process. The ability to follow a material or product through all stages of the supply and distribution chain is vital to consumers' safety. A fast response to food safety issues not only helps protect public health and safety, but is instrumental in protecting the viability and longevity of an organization and its reputation.

For retailers of private label products, traceability also provides important information on the quality aspect of the finished good. If a particular product receives rave reviews, manufacturers can pinpoint the farms and their specific varieties that contributed to its superiority, allowing manufacturers to refine their recipes. Likewise, products that underwhelm consumers can be evaluated down to the suppliers, and recipes again can be tweaked to make a more palatable finished product.

Quality From Farm to Fork

Fundamentally, choosing a supplier comes down to need, availability, qualifications, and price. Within these parameters, there is room for implementing practices that can help protect the integrity of a sourced product and, ultimately, the final product delivered to consumers. Evaluate all partners closely and maintain a commitment to frequent audits to ensure quality from farm to fork. ■

Boyd is FSQA manager of Trailblazer Foods, which produces co-pack, private label, and branded products. Reach him at tom.boyd@tbfoods.com. **Jackson** is director of purchasing for Trailblazer. Reach him at jim.jackson@tbfoods.com.

Special Report

Cadmium: A Clandestine Threat to Food Safety

This poisonous heavy metal is occurring at increasing concentrations in agricultural systems

BY **NICK KIM, PHD** AND **BRETT ROBINSON, PHD**

Cadmium (Cd) is a naturally occurring chemical element that is normally present in our bodies at low concentrations. Most of the Cd that we take in each day is delivered in food. With the exception of smokers and occupationally exposed groups, food usually accounts for over 90 percent of the Cd absorbed by members of the general population.

Cd is both non-essential and highly toxic in mammals. At a biochemical level it appears that we could live without Cd, if that were possible to arrange. The high toxicity of Cd refers to its capacity as an effective poison at low dose. Exposure to a sufficient dose of Cd over a short time period is capable of causing acute poisoning with or without subsequent fatality. The acute lethal dose to humans can be as little as 0.35 grams by ingestion. Death from this cause is not rapid, occurring between 24 hours to two weeks later. However, food safety risks of Cd are in another category entirely. Here doses are measured in millionths of a gram per day, and the risks are not immediate but rather relate to the long-term consequence of cumulative exposure.

Cd is one of the best examples that we have of a biologically cumulative substance. With food as a constant daily source, and loss of each daily dose taking between 20 to 40 years, the amount of Cd retained in a person's body gradually increases with age, from an estimated 1 millionth of a gram at birth to perhaps 15 to 80 milligrams (mg) by age 50, depending on personal history. About half (47 percent) of this accumulated Cd is retained in the liver and kidneys due to the presence of a metal-binding protein called metallothionein; a further three percent is shared between the lungs and pancreas, and the remaining 50 percent becomes more or less evenly distributed among the other tissues.

Unsurprisingly, the first reliable toxic effect of Cd accumulation in the body is the point where the burden of Cd in kidneys is sufficient to induce a change in kidney function. This toxicological endpoint is the focus of tolerable intake limits promulgated by the World Health Organization (0.025 mg of Cd per kilogram (kg) of body weight per month), and its science advisory body European Food Safety Authority (EFSA) (equivalent to 0.0108 mg/kg of body weight/month). The limits essentially represent the point at which the earliest onset of a change in kidney function may be starting to occur in post-50 year olds.

For contaminants that do not primarily act as carcinogens, regulatory bodies set tolerable intake limits by first determining the most sensitive toxicological consequence and then working backwards. It is unclear whether Cd should be treated in this way because some evidence exists that Cd may increase rates of breast and

(Continued on p. 50)

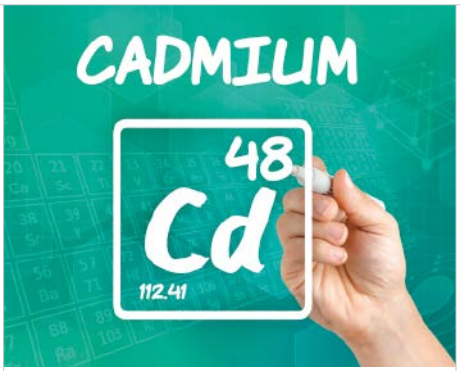
(Continued from p. 49)

testicular cancers. The kidney is currently regarded the primary target organ of Cd toxicity with tolerable intake limits based on changes to kidney function, but a future change in approach may result in still lower recommended limits.

Another, much harder, problem exists that is likely to prevent tolerable intake limits from being reduced any further than the EFSA-recommended current figure. This is that at ordinary levels of Cd in foods, we are already hitting against the kidney-function threshold. The preferred toxicological approach for residues and contaminants in the diet is to apply an uncertainty ("safety") factor to the lowest observed effects level to allow for inter-species and individual human variability, of perhaps 100. For Cd there is no such safety factor: The first onset of apparently toxic effects does appear to occur at the upper end of the usual intake range.

Recently, EFSA has released a set of "risk-based" food standards for Cd that, if adhered to and averaged across typical diets, would help achieve compliance with their recommended tolerable intake limit for Cd. The shift to risk-based food standards in recent decades has been a welcome development because many of older food standards were not overtly linked to tolerable intakes (toxicity is defined by the dose), or if they had been derived on this basis, the process was obscure. For food producers, these and other pre-existing food standards for Cd primarily represent a product compliance and trade risk. With a new set of food standards, it is likely that European regulators and markets will be placing a heavier emphasis on food compliance monitoring for Cd in the future.

Most dietary Cd comes from foods with elevated Cd concentrations that are consumed in significant amounts. These include cereals, vegetables, nuts, starchy roots or potatoes, and some meat products. Vegetarians have higher dietary exposures, as do regular consumers of bivalve mollusks and wild mushrooms. Smokers double their overall exposure, because tobacco contains significant Cd and the lungs are efficient at absorbing it. Together, ensuring compliance with tolerable intake limits and food standards will ensure the risk from Cd exposure from food is tolerably low.



There is Only One Problem

Most Cd in food comes from the soil where crops are grown and animals are raised. As a chemical element, Cd is present at low concentrations in all soils. However, human activities are causing soil Cd concentrations to increase, which results in increased Cd concentrations in food. While industrial activity, waste disposal, and mining can result in localized soil contamination, fertilizers and soil conditioners are the most important source of Cd in food-producing soils.

Elevated Cd concentrations are often associated with sources of phosphorus (P), an essential plant nutrient. Humanity needs to add P to soil to maintain productivity and feed an ever-growing population. P is added to soil via fertilizers, effluents, and sludge. These materials can contain Cd as an unwanted passenger that cannot easily be removed. The ultimate source of P is phosphate rock, a non-renewable resource that is mined and processed to give fertilizers (for example, superphosphate fertilizer). Geologically, Cd is co-deposited with P and phosphate rock can have over 500 mg of Cd for every kg of P. While the Cd concentration of phosphate rock varies, low-Cd sources of this mineral are mined preferentially, command a premium price, and will eventually be exhausted. In many countries like New Zealand, current P and Cd levels in many agricultural soils are now four to six times higher than their natural concentrations. Just as the majority of P in our diets could now be traced back to agricultural use of phosphate fertilizers, it is likely that most dietary Cd now also originates from this same source.

Municipal effluents and biosolids (sewage sludge) can be used effectively as P-containing soil conditioners. However, these materials also contain elevated Cd concentrations, along with other potential soil contaminants, particularly if there are industrial inflows into the sewage treatment plant.

Once added to soil, Cd binds strongly to soil particles, causing this toxic element to accumulate with each fertilizer application. Only small amounts of Cd are lost from the soil via surface runoff (with fertilizer runoff) and leaching, which is not significant until very high soil Cd concentrations are reached. The rate of Cd accumulation in soil depends on the concentration of Cd in the fertilizer. Low-cost fertilizers and effluents used by poor countries often have higher Cd concentrations, resulting in a more rapid buildup of this toxic metal in soil.

Plant roots can cause soil particles to release bound Cd, resulting in Cd entering the root and then the shoots of the plant. Grazing animals may consume the Cd-containing plant or, in some cases, ingest small amounts of soil directly. As with humans, the highest Cd concentrations in grazing animals are found in the kidneys and liver. Fortunately, there are no reports of muscle or milk products containing concerning Cd concentrations.

There is a large variation in the ability of plants to take up Cd from soil. Leafy greens such as lettuce and spinach have the highest Cd concentrations, while grains tend to have the lowest. That said, Cd concentrations in grains are of concern because they can represent a large proportion of the diet.

Managing Cd Concentrations in Food

Reducing or reversing the accumulation of Cd in soil requires the reduction of Cd applied with phosphate fertilizers. Removing Cd from phosphate fertilizers would halt further increases in the Cd concentrations of most agricultural soils. Unfortunately, there is no cheap way of removing Cd during fertilizer production.

In most cases, reducing the amount of phosphate fertilizer applied would result in an unacceptable drop in productivity. A characteristic of phosphate in soil is that it becomes immobilized and unavailable for plants, thus requiring additional fertilizer applications and further Cd accumulation. One line of research to reduce the reliance on phosphate fertilizers is investigating methods of liberating immobilized phos-

phate by using selected crop varieties or other soil amendments.

Sourcing phosphate rock with a lower Cd concentration reduces the amount of Cd added to soil. For example, most Cd in New Zealand's pastoral soils come from the application of superphosphate made from Nauru phosphate rock, which contained ca. 550 mg of Cd for each kg of P. Subsequently, the fertilizer industry has reduced the Cd concentration in fertilizers to less than 280 mg Cd/kg P by using phosphate rock from other locations. To avoid the accumulation of Cd in soil, phosphate fertilizers would need to contain less than 50 mg Cd/kg P. Further exploration and innovation in mining may yield fertilizers with even lower Cd concentrations. An example is the potential source of low-Cd phosphate in the Chatham Rise, off the cost of New Zealand. Accessing this resource has the technical and environmental challenges associated with undersea mining.

Most Cd in agricultural soil is bound within the top 10 centimeters. Therefore, plowing the soil will dilute the Cd within the soil profile. Plowing can reduce plant Cd uptake by moving the Cd to a zone of lower root density. This dilution effect increases at greater plough depths. However, continued application of Cd-laden fertilizers will eventually increase the Cd concentration in the entire soil profile.

Cd-contaminated soil cannot easily be cleansed. There are no commercially available techniques to remove Cd from contaminated soil at a cost that is less than the value of the agricultural land. Extracting the Cd using fast-growing plants such as willow may work in principle, but it is unclear whether this will ever be a commercially viable technology for farmers.

The amount of Cd that is taken up by plants and subsequently enter food products is dependent not only on the total Cd in the soil, but also on a plethora of other soil factors and plant factors. Some of these factors can be managed to reduce Cd concentrations in food. There is considerable variation in the Cd uptake among plant varieties. Selective breeding or genetic manipulation can be used to obtain plant varieties that take up low concentrations of Cd.

Plants in acid soils, soils with low organic matter, or soils that are high in chloride more readily take up Cd. Liming to reduce soil acidity can effectively reduce Cd uptake in some soils, but not others. However, liming is a blunt instrument: Over-liming can induce deficiencies of essential nutrients.

Adding some types of organic matter to soil can effectively reduce plant-Cd uptake. There is variation in the effectiveness of various types of organic matter in reducing plant-Cd uptake. Elucidating the critical factors for such Cd immobilization is an ongoing area of research. Plants take up more Cd from soils that are deficient in the essential micronutrient zinc (Zn). Alleviating Zn deficiency in soil may reduce plant Cd uptake and increase the Zn concentration in foods. This has the double benefit of alleviating Zn deficiency in people (which affects some two billion worldwide) and reducing the toxicity of Cd in Zn-deficient people.

Managing such plant and soil factors can reduce the Cd concentrations in food over the short term. While these measures do not stop the accumulation of Cd in the soil, they can extend the time that food production can safely occur on Cd-contaminated soils. This gives additional time for the development of low Cd fertilizers, or new soil cleansing techniques.

The Conundrum

While Cd concentrations in agricultural soils are increasing and Cd concentrations in some foods are nearing food standards, there are no reports of widespread Cd intoxication in the general population. In many agricultural lands, food production can probably continue apace without a widespread health calamity. However, over the medium term, continued accumulation Cd of agricultural soils is unsustainable because the upper end of current dietary Cd intakes are already commensurate with tolerable intake limits, and regulators will be moving to ensure that Cd in foods stay as low as reasonably achievable. Modifications to soil and plant factors can soften the impact of Cd accumulation in soils, and potentially work to reduce Cd in both individual foods and the whole diets, but the benefits of this work will ultimately be lost if Cd continues to strongly accumulate in growing soils. Therefore, a primary goal for agriculturalists should be to move to a steady-state condition, where annual inputs of new Cd to soils are no larger than losses.

The immediate issues for food producing countries are that food exports may be blocked if food standards are exceeded and the image of the country as a safe food producer may be tarnished. For countries with protectionist governments, Cd concentrations in foods may be a useful means of circumventing the World Trade Organization and imposing non-tariff trade barriers to protect local producers, even if the local produce also contains high Cd concentrations.

Any management decisions or regulations that are designed to reduce Cd concentrations in food need to be balanced against the cost of food production and the need to feed a growing population. In the meantime, the clandestine threat that Cd poses to food safety will inexorably increase. ■

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REFERENCES FURNISHED UPON REQUEST

Itai-itai Disease

One serious case of environmental Cd poisoning first focused scientific and regulatory attention on the possibility that long-term accumulation of Cd could cause serious harm. Between 1910 and the late 1940s, several hundred people from villages on the banks of the Jinzū River, Toyama Prefecture, Japan suffered from chronic Cd poisoning. Among other sources, Cd fumes and particulate matter emitted from a nearby mining company caused an excessive accumulation of Cd in soils of a farming community. Rice and soybeans grown in these soils contained high concentrations of Cd (1 to 3 mg/kg). Cd was not recognized as the cause until the mid-1950s. It was typically 30 to 40 years before the onset of symptoms, the most prominent of which was that the victim's bones fractured under slight pressure due to their decalcification and subsequent softening. The disease was extremely painful, and the sickness became known as Itai-itai disease, variously translated "it hurts-it hurts" or "ouch-ouch." By the end of 1965, some 100 deaths had resulted from disease.—*N.K. & B.R.*

NEW PRODUCTS

Cold Storage Monitoring System

The Sentinel system remotely monitors freezers and refrigerators to protect valuable food assets and cold storage equipment. It is ideal for food manufacturing, processing and storage facilities, research and testing laboratories, and food service and retail locations. System monitors up to 12 different environmental and equipment status conditions, including temperature, humidity, power failure, and water detection. When the system identifies issues, it instantly sends alerts via phone, text, or email over standard Internet connection. It also delivers daily event reports. Users can access information and make system changes from any web-enabled device. The system stores all readings in the cloud. **Sensaphone, 877-373-2700, www.sensaphone.com.**

Aerobic Bacteria Indicator Test

The 3M Petrifilm Rapid Aerobic Count Plate can detect aerobic bacteria counts in just 24 hours for most food matrices. It offers technology that reduces the impact of spreader colonies and a simplified inoculation area to drive greater efficiency and reduce costly retesting and delayed results. Plate also leverages a dual-sensing indicator technology for easier enumeration of colonies in raw material, in-process, and finished product food testing as well as environmental air, swab, or surface contact testing. The test has received certification from the AOAC International PTM program inserts. **3M Food Safety, 800-328-6553, www.3M.com/foodsafety.**

Laminating Film

SecuraShield laminating films now offer antibacterial protection through Biomaster technology to provide security and protection for various printed documents, graphics, and signage. The new film inhibits the growth of harmful bacteria by releasing silver ions. A bacterium landing on the Biomaster protected surface is unable to replicate and therefore it dies. The technology works 24 hours a day to inhibit the growth of microbes and has been proven to be effective on at least 20 organisms. In independent tests, SecuraShield with Biomaster film was found to reduce the levels of *E. coli* and *Staphylococcus aureus* by over 99%. **SecuraSeal, www.securaseal.co.uk.**

Meat Packing Software

SIMBA 2015 is designed to provide fish, meat, and poultry processors the ability to process, label, and track their products. The customizable SIMBA (Specialized Inventory Management with Barcode Accuracy) system can be integrated to most scales for proper weight measurements and it tracks by-products to multiple locations. SIMBA also provides yield amounts. A production line worker is able to change content of product labels with a fingertip on the computer or touchscreen, capturing product weight information and printing a label with a barcode identifier for that case or carton. **Dynamic Systems Inc., 800-342-3999, www.dynamic-systemsinc.com.**

Salmonella Environmental Monitoring Test

InSite Salmonella is a rapid and colorimetric *Salmonella* species test for environmental surfaces. It's a self-contained, ready-to-use swab test that contains a specialized liquid medium that changes color when *Salmonella* species are present in the sample. A color change from purple to bright yellow indicates presence, with positive results in as early as 24 hours from sample collection. The device's design eliminates the need for any special preparation, measurement, or enrichment outside the test device, simplifying the assay so any level user can successfully run the test. **Hygiena, 888-494-4362, www.hygiena.com.**

In Other Product News

Romer Labs's RapidChek *Listeria* Next-Day test system earns PTM certification from AOAC Research Institute for various ready-to-eat foods with a 27 to 48 hour enrichment.

The Health Canada Microbiological Methods Committee extends its approval of the **DuPont** BAX System Real-Time PCR Assay for *E. coli* O157:H7 in the *Compendium of Analytical Methods* for testing composited samples of ground beef weighing up to 375 g.

The USDA recertifies **Dorner Manufacturing's** AquaPruf 7400 Ultimate Series conveyor platform for meeting all hygiene requirements for the design of mechanical belt conveyors used in meat and poultry processing, as outlined in NSF/ANSI/3-A 114159-3-2010.

Silliker Laboratories formally adapts **Invisible Sentinel's** *Veriflow* diagnostic technology in its labs worldwide.

Advertiser Directory

ADVERTISER	PAGE
Bunting Magnetics	22
Diamond V	39
Eppendorf North America	56
Food Safety Summit	55
Food Safety Summit	Insert
Grocery Manufacturers Association	29
Invisible Sentinel	4
Lamitech	21
Nasco	17
Neogen	45
Roka Bioscience	9
Romer Labs	36
Teledyne Tekmar	24
Sigma-Aldrich	3
Steritech	2
Union Jack Tools	53
United Fresh	41
Waters	7

Events

MARCH

8-12
Pittcon
New Orleans, La.
Visit http://pittcon.org.

9
FSMA Supplementals Regulation Update
Logan, Utah
Visit www.usu.edu/westcent.

16
Whole Genome Sequencing for Food Safety—Opportunities and Applications to the Food Industry
Bedford Park, Ill.
Visit https://ifsh-wgs-registration.eventbrite.com or call 708- 563-8278.

25-26
Implementing SQF Systems in Food Manufacturing Operations
Eagan, Minn.
Call 888-330-6445 ext. 702.

APRIL

8-10
Thermal Processing of Ready-To-Eat Meat Products
Columbus, Ohio
Visit http://tinyurl.com/n29y6wy or call 614-292-4877.

13-15
17th International Halal Food Conference
(Schaumburg, Ill.)
Visit http://ifanca.org/pages/Conference.aspx or call 847-993-0034.

28-30
Food Safety Summit
Baltimore, Md.
Visit www.foodsafetysummit.com.

MAY

19-21
Food Microbiology Short Course
University Park, Penn.
Visit http://agsci.psu.edu/foodmicro or call 877-778-2937.

30-2
asm2015
New Orleans, La.
Visit http://gm.asm.org.

JUNE

1-4
Fundamental of Food Science
University Park, Pa.
Visit http://agsci.psu.edu/fundamentals or call 877-778-2937.

8-10
United Fresh
Chicago, Ill.
Visit www.unitedfresh.org.

9-11
Food and Airborne Fungi and Mycotoxins Short Courses
University Park, Penn.
Visit http://agsci.psu.edu/fungi-mycotoxins or call 877-778-2937.

16-18
49th Annual Microwave Power Symposium – IMPI 49
San Diego, Calif.
Visit http://impi.org/symposium-short-courses/ or call 804-559-6667.

JULY

11-14
IFT
Chicago, Ill.
Visit http://www.am-fe.ift.org/cms/.

SCIENTIFIC FINDINGS

For access to complete articles mentioned below, go to the "Scientific Findings" section of the February/March issue at www.foodqualityandsafety.com.

ARTICLE: Quality and Safety Attributes of Afghan Raisins Before and After Processing

Raisins are an important export commodity for Afghanistan; however, Afghan packers are unable to export to markets seeking high-quality products due to limited knowledge regarding their quality and safety. The minimal analysis and availability of data for Afghan raisin safety and quality levels hinder the ability of Afghan raisin packers to choose which factors they should focus their efforts to improve raisin quality. In this study, the quality and safety aspects of pre-, semi-, and post-processed Afghan raisins were evaluated from multiple production lots in order to partially fill this data gap. *Food Science & Nutrition, Volume 3, Issue 1, pages 56–64, January 2015.*

ARTICLE: Exploring Natural Selection to Guide Breeding for Agriculture

Agriculture faces increasing global demand for food from population growth and strong growth in per capita consumption due to economic development. It is widely accepted that this food needs to be produced from a similar area of land to that currently under cultivation, establishing the need to satisfy demands for more food by increasing agricultural productivity by crop breeding and improved crop management. Analysis of current growth in productivity for major crop species suggests that productivity growth will not be sufficient to satisfy the predicted growth. More aggressive innovation in plant breeding is a major option that may help to close the gap between the growth rates of production and demand. ***Plant Biotechnology Journal, Volume 12, Issue 6, pages 655–662, August 2014.***

ARTICLE: Functional Beverages—The Emerging Side of Functional Foods

There's been growing recognition of the key role of foods and beverages in disease prevention and treatment. Thus, the production and consumption of functional foods has gained much importance as they provide a health benefit beyond the basic nutritional functions. Currently, beverages are the most active functional food category because of convenience and possibility to meet consumer demands for container contents, size, shape, and appearance, as well as ease of distribution and storage for refrigerated and shelf-stable products. Moreover, they are ideal at delivering means for nutrients and bioactive compounds including antioxidants, plant extracts, and fiber, prebiotics, and probiotics. However, in most cases, specific concerns have been raised over their safety. This review reports on the scientific advances in the emerging area of functional beverages with a focus on commercially available products, as well as on the potential health benefits. *Comprehensive Reviews in Food Science and Food Safety, Volume 13, Issue 6, pages 1192–1206, November 2014.*

ARTICLE: Predictive Microbiology Coupled with Gas (O_2/CO_2) Transfer in Food/Packaging System

Coupling gas transfer with predictive microbiology is essential to rationally design modified atmosphere packaging, or MAP, strategies to ensure and guarantee food safety. Nowadays, these strategies are generally empirically built and over-sized since packaging material with high barrier properties is often chosen by default even if such a high level of protection is not systematically required. Protection strategies could be improved using rational sizing based on quantitative analysis and mathematical modeling of mass transfer. This paper aims at reviewing the current knowledge available for developing such a tool and the further research needed. *Comprehensive Reviews in Food Science and Food Safety, Volume 14, Issue 1, pages 1–21, January 2015.*

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