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Volume 20 Number 6
DECEMBER/JANUARY 2014

Food Quality & Safety

FARM TO FORK SAFETY

MAKING FOOD SAFER THROUGH LAW AND TECHNOLOGY

As efforts for new legislation emerged during 2013, innovative technologies and services were also introduced to meet the growing demands put upon food processors

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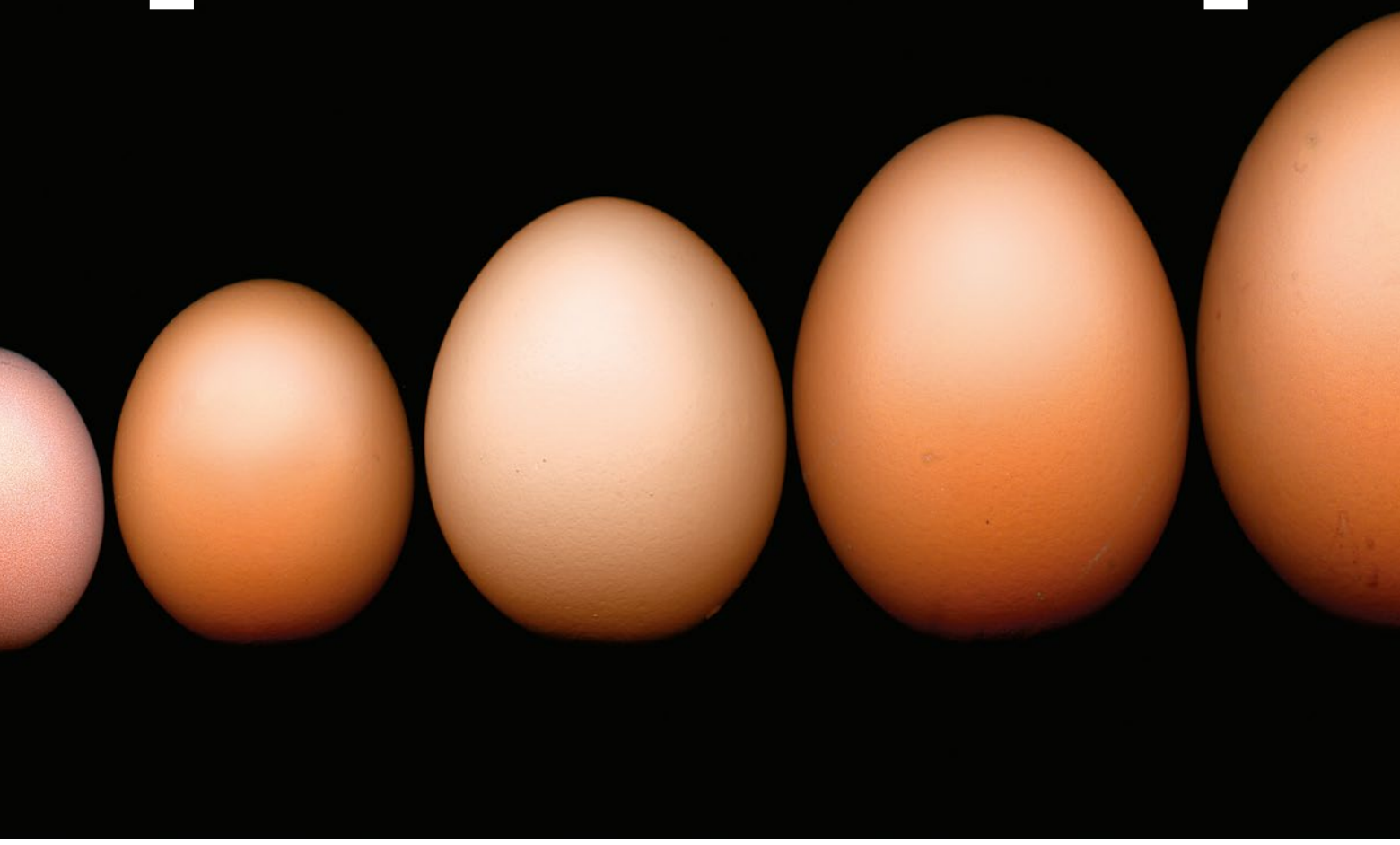

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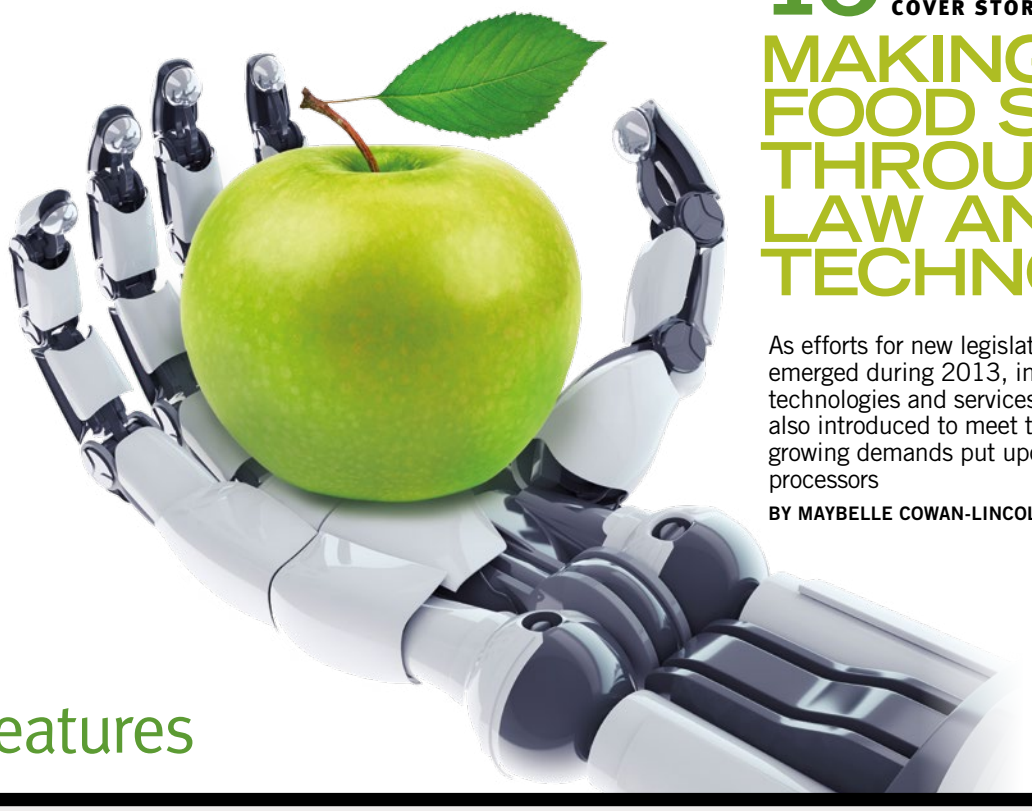

Features

Special Report

Safety & Sanitation

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From The Editor

During the Food ingredient Europe (FiE) show in November, Innova Market Insights presented its top 10 food and beverage trends for 2014. Retaining consumer trust topped the list. The "You Can Trust Us" trend centers around the recent food safety scares and scandals that have crippled consumer confidence and the fact that companies have their work cut out for them in order to regain consumer trust. As a result, Innova predicts that ingredient origin will be used as a marketing tool and ultimately the consumer should be able to benefit from higher quality foods that are clearly traceable.

While progress has been made during 2013 in improving the traceability of foods in the supply chain, Innova brings attention to the need for products that are traceable from the consumer's point of view in 2014.

"Traceability is high on the agenda and manufacturers are actively marketing this to consumers," says Lu Ann Williams, director of innovation at Innova Market Insights. "For example, global product launch activity featuring the word 'origin' for claims purposes increased by 45 percent for the first half of 2013 compared to the second half of 2012, with further growth anticipated."

General initiatives geared toward consumer-level traceability are indeed emerging. One of the more popular solutions is the use of QR codes. Shoppers can go to the grocery store, grab a package of tomatoes, scan the QR code with their smartphone, and instantly know exactly where and how the tomatoes were grown, when they were harvested, and if the product happens to be subject to a recall.

The U.S. Farmers and Ranchers Alliance's recent "Transparency and Consumer Trust Survey" finds that nearly 60 percent of consumers think it is "extremely important" for grocery stores and restaurants to provide information about the way the food they sell is grown and raised. And this demand for transparency isn't going away anytime soon. As the survey points out, younger shoppers (ages 21 to 29), or the "transparency generation," are more likely to purchase one food item over another based on which item includes more information about its origin.

It's apparent that if you're not offering *some* level of consumer traceability, the public will grow leery. There isn't a specific piece of information consumers are looking for, just information in general—whether it's a block of cheese carrying an origin claim or finding out which fisherman caught their salmon. Giving them any relevant and true insights about where their food comes from and how it was raised will go a long way into regaining consumer trust.

Marian Zboraj
Editor

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FARM TO FORK SAFETY

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NEWS & NOTES

Global Food Traceability Center

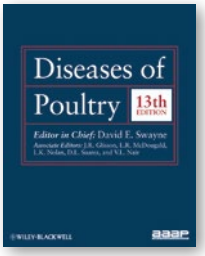
In September, the Institute of Food Technologists (IFT) officially launched the Global Food Traceability Center at a press conference with IFT president Janet Collins at the National Press Club in Washington, D.C. The Center will serve as an authoritative, scientific, and unbiased source for food traceability. Guided by an Advisory Counsel, the Center will generate knowledge that addresses research gaps and deliver applied research, objective advice, and practical expertise about food product traceability and data collaboration for private benefit and public good.

Food Protection Program Portal

The Association of Food & Drug Officials' (AFDO) Food Protection Program Portal is available to all food safety regulatory officials. The portal is located at www.afdo.org/fppp and can be used by food safety regulatory officials regardless of their AFDO membership status. It is designed to provide officials with useful information about food safety regulatory programs, pending and/or recently passed state legislation relating to food safety. Currently the portal contains license fees, inspection frequency policies, inspector to establishment ratio, 2012 and 2013 enacted state food safety laws, proposed state food safety legislation, and updates on federal legislation.

SCS Global Testing Services

According to SCS Global Services, its newly created SCS Global Testing Services will showcase expanded laboratory capabilities and competitive pricing, offering faster and more comprehensive laboratory services. SCS Global Testing Services will help growers, packers, shippers, distributors, and retailers achieve their product and process analytical and certification objectives. Lab testing and analytical services include pesticide residues, industrial contaminants, microbiological contaminants, nutrients and antioxidants, facility/environmental, GMO, gluten free, and food quality/sensory evaluations. Certification programs that can take advantage of testing include Organic, Pesticide Residue Free, and more.



Diseases of Poultry

Published in partnership with the American Association of Avian Pathologists, Wiley's latest edition of *Diseases of Poultry* examines the many aspects of poultry health and diseases, including pathogenesis, diagnostics, epidemiology, and control methods. The 13th Edition adds new diagnostic methods and a chapter on the importance of zoonotic infections for poultry pathogens, in addition to new photographs and discussion of conceptual operational biosecurity and disease control in organic production systems. The book is organized by disease type and offers detailed coverage of the history, etiology, pathobiology, diagnosis, and intervention strategies, as well as the economic and public health significance.

Creation of The Acheson Group

David Acheson, MD, former associate commissioner for foods at FDA and chief medical officer at the USDA FSIS, forms The Acheson Group (TAG)—a strategic consulting firm for food and beverage companies and those providing technical support to the food industry. TAG's service offerings are focused on four areas: Strategic Consulting and Regulatory Support, Crisis and Recall Support, Supplier Risk/Raw Material Risk Management, and Facility Risk Management.

IFPTI and RAPS Receive FDA Grant

The International Food Protection Training Institute (IFPTI) and the Regulatory Affairs Professionals Society (RAPS) receive a grant from FDA to address the workforce capacity issues facing food and drug regulators around the world, particularly among low-and middle-income countries. The 12-month project will focus on three major outcomes aimed at building a competent global regulatory workforce: Define the core competencies of a regulatory professional, develop a competency based curriculum framework, and create a gap assessment tool. RAPS and IFPTI will work closely with the World Health Organization and other global organizations.

Business Briefs

Silliker, a Mérieux NutriSciences company, celebrates the grand opening of its new analytical lab in Querétaro, Mexico.

Alchemy Systems merges with **Catalyst Awareness,** a loss prevention and health and safety communication company, to enable Alchemy to increase its offerings to the food retail market.

LabCentral, the fully equipped and resourced lab and office facility in the Cambridge Biotech Innovation Hub, adds **Eppendorf North America** as a major sponsor.

BT9 expands its international cold chain monitoring business with the opening of a new office in Los Angeles, Calif.

Chobani and **Cornell University** partner together to promote innovation in dairy and food science, made possible by a $1.5 million gift from Chobani to the University.

The **Food Marketing Institute** and **United Fresh Produce Association** announce a three-year agreement to co-locate the organizations' respective trade shows: United Fresh 2014 and FMI Connect.

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Washington Report

Systems Recognition: Designation Will Be Challenging for Most Countries

If a foreign country is able to achieve a 'comparable' food safety system, it can cut through the regulatory red tape and make it easier for its food producers to export to the U.S. | BY **TED AGRES**

As part of its implementation of the Food Safety Modernization Act's (FSMA) Foreign Supplier Verification Program (FSVP), the FDA is developing procedures for evaluating the food safety and inspection regimes of foreign countries to determine whether they are "comparable" with those of the U.S. Obtaining "comparable" food safety status from the FDA will be beneficial because food exporters and U.S. importers will enjoy a streamlined process devoid of much of the additional red tape and scrutiny expected under FSMA. So far, only New Zealand has been granted this coveted status, but the FDA has pilot projects underway with Canada and the European Union to evaluate how it will perform "systems recognition assessment" (previously called "comparability assessment") going forward. The agency is also seeking comments from foreign countries, U.S. companies, and other stakeholders on its proposed methodology.

"Under the FSVP proposal, there is a provision that if you are importing from a 'recognized' country—such as New Zealand right now—the only verification you have to do for that supplier is get a certificate from the government that it is in good standing," says Joseph Levitt, a partner with the Hogan Lovells law firm in Washington, D.C. and a former director of FDA's Center for Food Safety and Applied Nutrition (CFSAN). "That's an enormous savings of time and energy that companies can devote elsewhere."

The U.S. importer would be required to list its foreign supplier, identify itself at the point of entry, and ensure that FSVP records are available to the FDA, adds David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. "The value of systems recognition is that it adds economic positives by reducing burdens on both the private and public sectors," Dr. Acheson tells *Food Quality & Safety* magazine. "There are good reasons to do it, but it needs to be done right," he says.

Even FDA acknowledges that doing it right will be challenging. "Globally, there is substantial variation in the robustness of food safety systems, ranging from systems in the early stages of development to highly mature food safety systems. This variation heightens the challenge to FDA in developing effective import control systems," the agency says in an explanatory document posted September 5, 2013. Another challenge is that FDA must design a system that enhances imported food safety but doesn't violate World Trade Organization and other international agreements that prohibit foreign products from being held to tougher standards than domestically produced counterparts.

The corollary is also true, says Michael R. Taylor, FDA deputy commissioner for foods and veterinary medicine. "U.S. food producers and processors also have a stake in the safety of food and ingredients from overseas and rightly want to know that there's a level playing field—that imported food would have to meet the same safety standards as food produced in the U.S. under the new food safety rules," Taylor wrote in a recent online posting. "And it makes sense that European firms and governments are interested in the FSMA requirements we are developing because they want to maintain market access in the U.S.," he says.

A Promising Approach

Food safety experts generally laud the systems recognition approach. "This initiative by FDA holds a lot of promise if the agency is able to 'recognize' a number of other countries as having advanced food safety systems that are comparable to those of the U.S.," Levitt tells *Food Quality & Safety* magazine. "Only time will tell whether the New Zealand recognition is isolated or a preview of what's to come." This is a key point because even FDA officials think the program will have limited attractiveness.

"According to FDA officials, the agency expects a limited number of countries to seek comparability with the United States because, in part, most countries will not meet the FDA requirement that the foreign government's domestic and export food safety systems be comparable with the U.S. system for all their food products," says a September 2012 report by the congressional Government Accountability Office (GAO). While some countries have "robust" export certification programs in place for certain food products, such as seafood, their overall food safety and domestic production systems may not be comparable with those of the U.S. "Such countries would be more suited to apply for accreditation as a third party rather than seek overall systems comparability," FDA officials told GAO auditors.

FSMA requires FDA to establish a program for the Accreditation of Third-Party Auditors for foreign food facilities. In this, FDA will recognize accreditation bodies which, in turn, will accredit third-party auditors to conduct food safety audits and issue certifications for foreign facilities and food. A third-party auditor could be a foreign government, a foreign cooperative, or other third party as long as it has legal standing and meets other standards, such as for competency.

"FDA believes that comparability is a more efficient and appropriate tool for FDA to use in assessing whether a country's entire food safety system provides adequate assurances of comparable public health outcomes, and third-party certification is a more appropriate approach for FDA to use when assessing a particular segment of the food safety system," says Jim R. Esquea, assistant secretary for legislation at the Department of Health and Human Services, FDA's parent agency, in written comments to GAO.

GAO disagrees with FDA that the use of third parties is preferable to comparability assessments, noting that some foreign governments may object to being designated as a third party because of sovereignty issues. And then if they do agree to that designation, "there is a potential conflict of interest in having a government accreditation body accredit another government agency from the same country as a third party," GAO says, raising questions of bias.

GAO would prefer that FDA utilize systems recognition even for specific foods or subsets of food. This would be more comprehensive than a third-party accreditation arrangement, and would produce advantages similar to those realized by the FDA's Food Safety and Inspection Service (FSIS) and the E.U. from their use of stricter "equivalence" standards. "If FDA had a comparability assessment agreement with a foreign country, similar to an E.U. equivalence agreement, a foreign competent authority would address any identified problems and take regulatory actions across the supply chain, as necessary," GAO says.

"Equivalence" is a much higher standard than "comparability." When it comes to importing meat, poultry, and processed egg products into the U.S., FSIS evaluates whether a foreign country's food regulatory system employs equivalent sanitary measures that provide the same level of protection against food hazards as is achieved domestically. As of October 2013, FSIS had approved 34 countries including Albania, Argentina, Austria, Belgium, Brazil, Canada, Chile, China, Costa Rica, Croatia, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Honduras, Hungary, Iceland, Ireland, Israel, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Northern Ireland, Poland, Romania, San Marino, Spain, Sweden, and Uruguay.

"Trying to demonstrate equivalence for every food item would be impossible," Dr. Acheson says of systems recognition. "So FDA is taking a different tack of seeing whether public health protections in the foreign country are similar to those in the U.S. This gives the FDA leeway, but it is still a heavy lift and an onerous process."

Getting Recognized

FDA has outlined a multistep process it will use for recognition. After a country requests systems recognition, FDA will review its compliance history, trade volume, number of admission refusals and reasons, import alerts, and other information. FDA will then review these findings with food safety officials in that country. If they want to proceed, the officials will be asked to complete an International Comparability Assessment Tool (ICAT) to evaluate the extent to which the country satisfies standards in 10 areas: The regulatory foundation; training programs; inspection program; program assessment/inspection audit program; food-related illness and outbreaks; compliance and enforcement; industry and community relations; program resources; international communication and harmonization; and laboratory support.

"Under systems recognition we assess a country's entire food safety control system, from soup to nuts and every other food that FDA regulates," says Julie Callahan, an international policy manager at CFSAN. "Of course, how things look on paper doesn't always reflect how they work in practice. So we include onsite reviews as part of the systems recognition assessment process to see firsthand how a country implements the programs they've described in the ICAT," Callahan said in a recent online posting. The draft ICAT is modeled after FDA's 2010 U.S. Manufactured Food Regulatory Program Standards, a tool to evaluate the regulatory oversight of food facilities at the state level.

FDA's systems recognition pilot with New Zealand concluded with formal recognition in December 2012. A pilot with Canada on its food safety system is underway and a systems recognition pilot with the European Commission is attempting to see how that approach might help further equivalence assessments of each other's systems for shellfish. The FDA hopes to expand these efforts to more countries "in the near future," Callahan says.

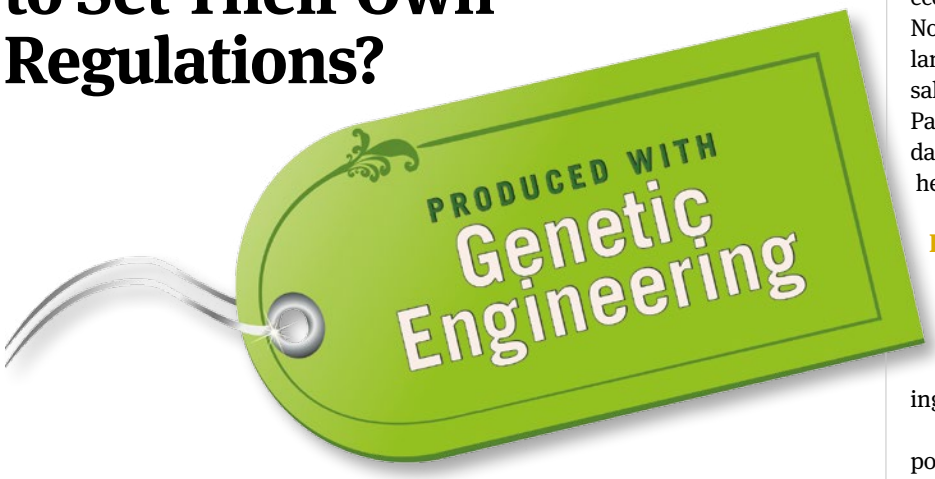
Some may be concerned about the potential for backlash should a country seek systems recognition but fail to get it. "Trade issues will get stirred up," Dr. Acheson says. "If, for example, FDA chooses not to recognize Mexico's food safety systems under FSMA, it may not go over too well. But if Mexico is smart, it will not request recognition because it knows what the answer will be."

Levitt, however, is not worried. "When this process is done, if similar countries are included as being 'recognized' as having advance food regulatory systems while other countries with less-sophisticated systems are not included, then it will be all right." ■

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

Industry Insights

GM Foods: Can We Afford for States to Set Their Own Regulations?



Besides unintended consumer consequences, food quality and safety managers would have to manage conflicting GMO labeling standards for identical products across multiple states

BY **DON BUTTE** AND **JEFFREY WHITESELL**

Food quality and safety managers have their necks on the line daily when it comes to managing their companies' quality and safety programs, including their product labeling. Should any of the current state initiatives to establish unique state standards for genetically modified organisms (GMO) and non-genetically modified organisms (NGMO) products become effective, their jobs will instantly become significantly more complicated.

Various ballot initiatives seeking to impose increased labeling requirements on GMO foods are being proposed in over 20 states. In June 2013, Connecticut became the first state to pass legislation requiring GM foods and foods containing GMOs be labeled as "produced with genetic engineering." Because of concerns about potential negative consequences, the bill includes a "trigger" provision that the labeling requirements would go into effect only after at least four other Northeastern states with a population of at least 20 million adopt similar requirements. Shortly thereafter, the Maine legislature passed a similar bill, also containing a "trigger" provision requiring labeling only if at least five neighboring states pass similar GMO legislation.

The Motivation

The *Oregonian*, an Oregon newspaper, recently reported that state lawmakers are studying eight bills focused on labeling GM foods, fish, and crops. One proposal bans the farming of such fish outright.

Oregon State Representative Paul Holvey, a sponsor of several GMO bills, told the newspaper, "I think consumers have a right to know and make their own decisions about these foods." Holvey said he became concerned about the issue after visiting Atlantic salmon fish farms in Washington and British Columbia. "Our fisheries are extremely important to the economy," he said. "If we allow the Pacific Northwest to become a mixed bag of Atlantic salmon and genetically engineered salmon, I think consumer confidence in Pacific salmon will be undermined and damage the industry." No mention of health concerns there.

Federal Preemption

While FDA regulations require labeling hundreds of food ingredients, additives, and processes, they currently don't contain any GMO labeling rules.

Any state legislation seeking to impose labeling requirements on GMOs will undoubtedly face litigation from various parties, primarily the food and agriculture industries. The first expected challenge to any such legislation is preemption by federal regulations. In other words, any state legislation is trumped by existing federal food labeling regulations, including the Federal Food, Drug, and Cosmetic Act (FDCA). Under the Supremacy Clause of the U.S. Constitution, state laws are invalidated if they "interfere with, or are contrary to, federal law."

Generally, state labeling requirements contradictory to federal regulations are preempted by federal regulations. But what if there are no contradictory federal regulations? Neither the FDCA nor the FDA currently have labeling requirements in place for these foods. FDCA prohibits only state labeling requirements that are "not identical" to federal regulations, and courts have upheld state labeling requirements that address areas not regulated by FDA. The federal government, including both Congress and FDA, has the power to silence the preemption issue once and for all and to halt all current and future state efforts to label GMO products. Regardless, no such federal bill has been passed and

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the FDA has shown no interest in becoming involved in this GMO labeling issue.

The food industry would prefer federal legislation for the labeling of GMO products rather than having to satisfy 50 different sets of regulations and incurring the expense of fighting these state regulations in the courts. Federal food labeling legislation would give the food industry one uniform standard to follow, and would permit one single label to be used in every state.

Right to Free Speech

Another significant obstacle state GMO legislation may face is infringement on food producers' First Amendment rights. No Constitutional "right to know" exists in the U.S. Any legislation either compelling food producers to include certain language on their products or banning certain language from being used could be vulnerable to a First Amendment challenge. The freedom of expression protects not only the right to speak, but also the right to abstain from speaking.

In order to survive a First Amendment challenge, a state legislative restriction on commercial speech (i.e., labeling requirements) must strike a balance between the new regulations and the producers' right to free speech while showing the state's interest in passing the legislation is substantial.

Past cases suggest that proposed legislation requiring food labeling to contain certain terms such as "genetically modified," absent a compelling state interest, may not survive a First Amendment challenge. Proponents of the new labeling standards assert the need to protect consumers' right to know the content of their food (i.e., to satisfy consumers' curiosity). They don't claim such labeling protects health or safety interests, likely because there's no scientific evidence GM foods materially differ from other food products.

Interstate Commerce Clause

Another major potential constitutional hurdle is the impact on interstate commerce—the free exchange of products between citizens of different states across state lines. Under the Commerce Clause of the U.S. Constitution, congress has the exclusive power "to regulate commerce with foreign nations, and among the several states" to ensure the free flow of commerce without local or state restrictions.

States have the right to regulate their own domestic commerce where there is no federal legislation in that area. But the exercise of that right cannot impede, discriminate against, or burden interstate commerce. If it does, the state and national interests fuelling the legislation must be weighed and a determination must be made as to whether the legislation oversteps the federal government's exclusive power. Legislation violates the Commerce Clause if either the alleged state interest served by the law is outweighed by the burden imposed on interstate commerce or if its discriminatory effect on out-of-state producers burdens interstate commerce.

In order for such regulations to survive an interstate commerce challenge, a legitimate state interest must be shown. But courts have repeatedly found, absent a legitimate health or safety concern, a state may not burden interstate commerce. Is consumer curiosity enough?

Costs of State Legislation

The advocates of state legislation claim consumers have a "right to know" what's in their food, despite the fact only 3 percent of Americans mention GMOs when asked what additional information they'd like to see on labels. However, the unexpected costs of states passing their own GMO labeling requirements will be significant. States will have to incur the substantial burden and costs of defending the regulations in court. Regardless of which states take on this legal fight, the taxpayers will pay millions in litigation costs and attorney fees with their tax dollars. On the other side, consumers will wind up paying the litigation costs for companies challenging these new labeling regulations in the form of higher food prices.

It's estimated 70 percent to 80 percent of the processed foods sold in the U.S. contain at least one GM ingredient, and according to the USDA, 88 percent of corn acreage, 94 percent of soybean acreage, and 95 percent of sugar beet acreage is genetically modified. It will be virtually impossible for food quality and safety managers to successfully manage a massive NGMO transition—assuming there are enough NGMO ingredients available.

What does all of this mean to food growers, manufacturers, marketers, and sellers? To small companies with sales contained primarily in one state, this may well be a boon to their top and bottom lines since it may limit competition. At the same time, if nearby states have different regulations, it will inhibit their growth beyond state boundaries. State-by-state labeling laws and definitions will result in a quality and safety management nightmare. It will also have a negative impact on both the top and bottom lines of medium and large food operations that will be forced to pass their increased costs onto consumers and even remove popular brands from the shelves.

Placing a GMO label on every package would likewise be virtually impossible as each state requires its own unique GMO language for food sold in their states.

As a nation, can we really afford the unintended consequences of letting 50 states go their own way on regulating our food supply? A select group of consumers comprising less than 5 percent of the population have the money and are willing to pay the increased price for organic and NGMOs even though the USDA states there's no proof these choices lead to better health. While they are free to make these choices, to impose the increased costs on the rest of the citizenry is unjust, begging the real question: Why are state governments and politicians spending political capital on GMO food regulations? It appears the *Oregonian* article tells the whole story. The GMO effort is primarily about economics—with the "health" claim used when convenient.

What was started by a few serious-minded people with the clear intent of improving our quality of food and health appears to have been hijacked by self-interest groups, politicians, and profiteers. Food quality and safety managers are in the right spot at the right time to steer the agenda away from politics and back toward food quality and safety. ■

Butte is a senior food executive and expert in supply chain management and efficiency with more than 30 years of experience. Reach him at dabpolo@aol.com. **Whitesell**, an attorney in Tucker Ellis LLP's Cleveland office, focuses on products liability, medical and legal malpractice, toxic torts, and securities and business litigation. Reach him at jeffrey.whitesell@tuckerellis.com.

WAIT, THERE'S MORE! To read this column in its entirety, go to December/January issue on www.foodquality.com and click on this article for expanded content.

MAKING FOOD SAFER THROUGH LAW AND TECHNOLOGY

As efforts for new legislation emerged during 2013, innovative technologies and services were also introduced to meet the growing demands put upon food processors

BY **MAYBELLE COWAN-LINCOLN**

The year 2013 was a big year for food safety in terms of advancements in testing, regulations, and equipment. Of course, food safety also made an impact across mainstream media headlines. One topic that proved most prevalent involved instances of food fraud—two men arrested in London as part of an investigation into beef adulterated with horsemeat; eight managers of the Toulouse, France-based company Spanghero, arrested for fraudulently supplying horsemeat labeled as beef to ready-made meal manufacturer Comigel; and over 900 people arrested in China for food safety violations, including 63 people who sold modified rat, mink, fox, and other meat as lamb. Food fraud, in the form of species misrepresentation, has become a global problem.

The issue here goes beyond deception. Animal species that are not destined to enter the food chain are not subject to the same safety standards as animals meant for human consumption. Their feed is not regulated and their meat not tested for pathogens. Also, veterinary medications can be an issue. For example, horses not raised for human consumption may have been given phenylbutazone, a substance linked to cancer in humans. The European Food

Safety Authority and the European Medicines Authority pointed out in a 2013 joint statement that a maximum threshold for carcinogen risk could not be identified; therefore, the substance is banned in animals destined to enter the food chain.

Although media coverage has focused on cases of meat fraud in Europe and Asia, U.S. consumers cannot be complacent about the integrity of their meat labeling. According to international food safety lawyer Cesare Varallo, publisher of www.foodlawlatest.com, "No one thought before the [European horsemeat] scandal that this could be a real problem, so no one checked for this specific risk." There were, however, other examples of food fraud brought to the American public's attention this year, encompassing products like fish, olive oil, fruit juices, and honey.

Species Verification

During the course of 2013, the U.S. FDA finally released the five proposed rules under the Food Safety Modernization Act (FSMA), one of which covers its vigilance over imported foods. Says Varallo, "The FDA rules on imported food are strongly oriented to prevent this type of fraud from happening. Every importer will follow a Foreign Supplier Verification Program to demonstrate that imported food has the same level of safety as domestic food."

The FSMA does not guarantee the absence of food fraud. However, DNA testing can affirm what species are contained in a piece of meat. Companies looking to verify their meat is not mislabeled may be interested in a product launched in August 2013. Lansing, Mich.-based company Neogen, providers of both ELISA (enzyme-linked immunosorbent assay) and PCR (polymerase chain reaction) species testing kits since 2009, introduced NeoSeek, a species identification lab service. To contract for the NeoSeek service, customers visit the Neogen website to request a test for the species of adulterant they are looking to find in their meat. Neogen will send out a sample shipping kit and the customer sends a 50 gram sample to Neogen's testing facilities in Lincoln, Neb. Gerry Broski, senior marketing director, food safety for Neogen, says, "We have engineered the sample submission process to be as painless as possible. The samples are shipped to the GeneSeek Lab, and within 48 hours you get an email with DNA-definitive results on raw or cooked samples."

NeoSeek detects adulteration at levels of 0.1 percent to 1 percent of mislabeled horse, pig, poultry, beef, or sheep meat, which corresponds to USDA MLG protocol of the levels at which food is considered adulterated. If the customer requires precise levels of the adulterant, quantitative results are available.

Looking at Allergens

Also in August 2013, the FDA published a definition of "gluten-free" to be used in voluntary food labeling. Previously there was no official federal definition for the term "gluten-free" used in claims. The new regulation sets a standard of no more than 20 parts per million (ppm) of gluten, a level that can be detected by scientifically validated, analytical methods. The agency chose this level because certain celiac researchers and some epidemiological evidence suggest most individuals with celiac disease can tolerate trace amounts of gluten in foods (including levels less than 20 ppm) without adverse health effects. FDA spokesman Arthur Whitmore explains, "The definition in the rule helps people with celiac disease and gluten sensitivity by setting a reliable and consistent standard for the claim on food products."

Although some concerns have been raised that certain people can experience adverse effects from levels lower than this, the Gluten Intolerance Group of North America and the Celiac Disease Foundation support the new definition. The FDA recommends individuals who are extremely sensitive to any amount of gluten should consult with their physicians to develop an appropriate diet plan.

One way for companies to ensure a product meets the new FDA standards for gluten-free is to certify it through the NSF Gluten-Free Certification Program. NSF International is an independent, global organization that certifies products for the food, water, health sciences, and consumer goods industries to minimize adverse health effects and protect the environment. The NSF Gluten-Free Certification Program verifies that certified products contain 20 ppm or less of gluten, in line with Codex Alimantarius Commission Standard, the European Commission Regulation Health Canada, and the FDA regulation. When certification is successfully completed, the product earns a NSF Gluten-Free label.

During an onsite NSF inspection for certification, a random sample is collected and tested using ELISA-based methods to establish gluten-free integrity at 10 ppm or less. (Testing for a significantly lower gluten threshold than certification requirement of 20 ppm or less takes into account the variability of ingredient lots and batches and ensures, as well as possible, the food being tested never exceeds the allowed ceiling of 20 ppm of gluten.) The inspector verifies that the manufacturing process prevents gluten contamination of products, and raw ingredients have been tested for gluten. The inspector also verifies the allergen affidavits and certificate of analysis, as well as confirms raw ingredients were sourced from QAI (Quality Assurance International) Gluten-Free suppliers.

According to Jaclyn Bowen, general manager of NSF International Agriculture and QAI, "A well-developed and well-executed gluten-management program goes hand in hand with other food safety management systems. Testing alone is not sufficient to ensure the gluten-free compliance of your product. An investment in a quality management system that evaluates supplier assurance, good manufacturing practices, and ongoing training is your best option to ensure your products reproducibly meet the requirements of the FDA Gluten-Free Final Rule."

The publication of the gluten-free definition draws more focus on the overall presence of various allergens. The year 2013 saw an advance in allergen testing born from a collaboration between Romer Labs of Tulin, Austria, and ifp Institüt fur Produktqualität of Berlin, Germany, when they launched the AgraQuant F.A.S.T. (Fast, Accurate, Simple Technology) ELISA test kit to meet the increasing number of restrictive government regulations.

Romer Labs gathered feedback from the food industry to help guide the development of the benefits of AgraQuant F.A.S.T. According to the company, it is currently the fastest allergen testing kit on the market, with an extraction time of one minute and an assay performance time of 30 minutes. A 1 gram sample is required, although Romer Labs recommends taking multiple samples that are well-homogenized then subsampled to ensure it is representative of the product. Two capsules, using a proprietary technology developed by ifp, are then added to the sample, one filled with extraction buffer and one with additional extraction enhancement substances. After 20 milliliters of hot water (80 degrees to 100 degrees Celsius) are added, the sample is shaken for 15 seconds so the capsules dis-

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solve and proteins from the sample are extracted. The sample is then filtered or centrifuged so it can be used for the ELISA assay.

In addition to its fast time to results, Elisabeth Halbmayr-Jech, technical manager with Romer Labs, points out, "AgraQuant F.A.S.T. allows the technician to use one extract over multiple test kits to look for several allergens. This feature adds to the speed of the process and reduces the chance for error. Also, the test kit requires very little training."

Testing for Pathogens

In 2013, Bio-Rad Laboratories, a Calif.-based food safety solutions provider, introduced a technology that marries process innovation and advanced data collection. The iQ-Check Prep is an automated PCR solution that tests for foodborne pathogens. The first element of the process is a line of highly nutritive broths that minimize enrichment time. After enrichment, the user takes samples from the broth and transfers them to a 96-deep well plate. The batch of samples is placed on the automated processing instrument which takes over the sample preparation and places it on the PCR plate. The user then removes the plate, seals it, and places it in the thermal cycler for PCR detection.

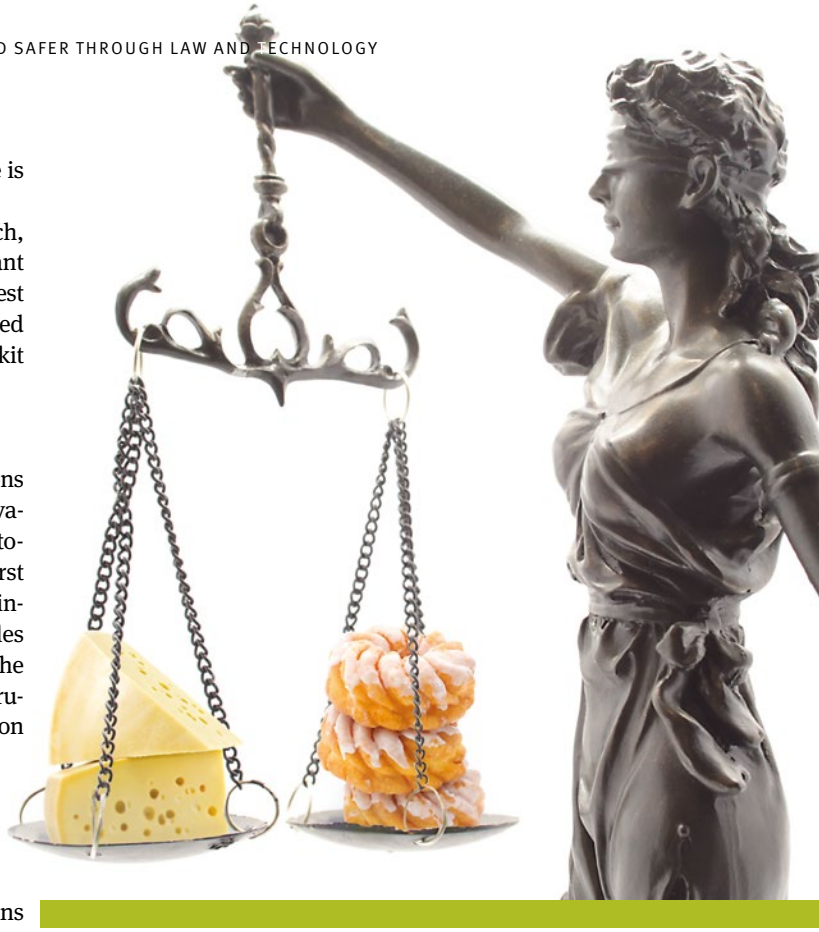
The system provides several advances, such as minimal handling of the sample to reduce error. In addition, the iQ-Check Prep uses air displacement pipettes that operate like plungers instead of a conventional vacuum system. This means there is no liquid passing through the system which could cause contamination. The instrument also features a liquid detection sensor that verifies if the lab technician did, in fact, transfer the liquid samples. The user can be confident therefore that a negative reading means that a sample is clean because no pathogenic bacteria are in the sample, not because there was no sample present to be tested.

This last innovation is part of the traceability capability the iQ-Check Prep offers. The machine documents each step of the process and exports information to the user's laboratory information management system. At a later date, users can look up previously tested samples and find that a sample was actually present in the instrument, as well as review the results of the PCR assay. This documentation is valuable to meet documentation requirements.

Offering a variety of pricing solutions for companies, Wendy Lauer, senior product manager of the Bio-Rad Food Science Division, explains, "We look at it from a process standpoint. We want to help our customers optimize their workflow and traceability, so we work with them to make sure it is a fit for their lab."

Another facet of FSMA is the requirement for preventative control systems modeled on Hazard Analysis and Critical Control Points (HACCP) for facilities that manufacture, process, pack, or hold food for human consumption. "We think that the proposed rule provides a science- and risk-based, as well as flexible, approach to preventing hazards in foods," states Jenny Scott, senior advisor, office of food safety of the FDA. "It is based on internationally recognized principles of HACCP and best practices of industry."

Preventing these food hazards would include sanitation controls. Providing HACCP management capabilities, BioControl Systems recently launched Lightning MVP Icon System to test for cleanliness through the detection of adenosine triphosphate (ATP), a molecule found in most food residues as well as bacteria, yeast, and mold. The system consists of a handheld device to take readings and PC software to run an integrated sanitation program.



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The handheld unit uses the following paths to test for pathogens or conditions that promote their growth.

Pathogens on Surfaces. A proprietary sampling device containing a luciferin/luciferase reagent swabs a surface. The reagent reacts with any ATP it finds on the swab to produce light. The Icon reads the light signal and interprets its intensity to determine where it falls within Pass/Warn/Fail parameters.

Pathogens in Rinse Water. A device designed specifically for testing liquids collects a rinse water sample that is tested by the Icon to ensure equipment has been thoroughly sanitized.

Conditions Conducive to Pathogen Growth. External probes to test for pH, temperature, and concentration can be connected via USB connection to the Icon. Acceptable thresholds for each can be entered into device and stored, and measurements are compared to these metrics to produce Pass/Fail results.

The Icon's color touchscreen identifies each test point by name, date, and time taken, and also displays the results. Icon can be connected to a PC through a USB port and the results uploaded to the Icon Dashboard software that contains widgets to report on the current state of test points as well as their historic readings.

Icon Dashboard can be a valuable tool for HACCP monitoring. According to Anita Kressner, vice president global sales and marketing, "The MVP Icon Dashboard software provides at-a-glance reporting of the most critical performance metrics of a sanitation program. Essential information including the number of samples taken and the retest rate is updated in the dashboard each time

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the MVP Icon is synched with the computer. The dashboard also displays a reminder for the date the next calibration is due, which can be done onsite."

Risk Management Technologies

FDA legislation centers around assessing and managing risk. A company called Battelle in Columbus, Ohio, has recently developed a technology called PRIA that can help the poultry industry in this endeavor. PRIA is actually based on Department of Homeland Security software that performs risk assessments using mathematical and statistical projections to map out the scope of the disaster should a biological or chemical attack assault the food supply chain. Because foodborne pathogens would follow the same path of distribution as a foodborne biological attack, the same risk assessment models can be used to identify the route and degree of damage of a pathogen.

PRIA can be used to model the outcomes of any safety measures a poultry company might potentially employ. A variety of alterations can be input, including *Salmonella* inoculations, an antimicrobial dip, or an initiative to prevent temperature abuse in distribution and retail. The program projects what changes would result downstream of the poultry company for each variable, allowing users to evaluate the outcomes and choose the most beneficial and most cost-effective improvements to be made. Brian Hawkins, senior research scientist at Battelle, explains, "You can look at these possibilities side by side and make a quantitative decision based on the impact. You can see by how much it will reduce projected illnesses or projected contamination." At press time, Battelle was currently working with two poultry companies to take the PRIA prototype to launch.

Despite the most stringent sanitation and testing standards, foodborne pathogens can find their way into commerce, resulting in recalls. To keep consumers as safe as possible, the agency randomly demands food processing companies to stage mock recalls. In one of these exercises, companies must be able to identify the location of each lot of food they have shipped within two to four hours.

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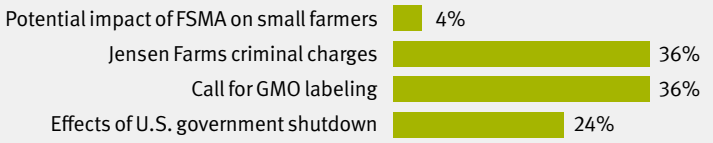

One of the challenges encountered during a food recall is locating where a particular lot number of raw ingredient has been used, thereby limiting the recall to strictly the contaminated food. Many manufacturing facilities are still using manual records, so in the event of a recall, finding the one paper that lists the final destination of an ingredient or finished product can be daunting. Often the company recalls everything on the shelf, doing deep and unnecessary damage to the brand. GE Intelligent Solutions, a division of General Electric, developed Proficy, a software package, to digitize this recordkeeping.

Compatible with multiple hardware and software products, Proficy collects data stored in the computer brain of each machine in the automated food processing factory including oven temperature, belt speed, and humidity, as well as data input by operators such as ingredient lot numbers. The program integrates the data, giving food suppliers a holistic "snapshot" of any moment or aspect of production. Moreover, if any problems arise, a warning is sent automatically to the person who needs to take appropriate corrective action. They can know in an instant if machinery was functioning properly, if conditions were correct, as well as where each ingredient and finished product wound up. According to Katie Moore, global industry manager, food and beverage for GE Intelligent Platforms, "Proficy is not just about collecting data for its own sake, but about collecting information seamlessly and getting it to the people who need it when they need it."

As we enter 2014, there's little doubt that the more comprehensive strategies adopted by food growers and processors will continue to offer food industry technology providers challenging, and potentially rewarding, opportunities for innovation. Though the full impact of FSMA has not yet been realized as the comment period for the final proposed rules are still ongoing, Scott reminds us that all the regulations promulgated by FSMA emphasize that the primary responsibility for food safety lies with the industry. ■

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Special Report

The Road Back to Trust

New Zealand-based Fonterra is striving to restore its reputation for food safety since the recent whey protein recall

BY **LINDA L. LEAKE, MS**

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It's a CEO's worst nightmare. You're 11,000 miles away from the office when your cellphone rings late at night. You see it's work calling. "Oh, oh," you exclaim. "It must be bad news. They wouldn't disturb me otherwise."

Theo Spierings lived this bad dream as clocks struck midnight in his native Netherlands on Thursday, August 1, 2013. The chief executive officer of Fonterra Co-operative Group Ltd. was back home for a relative's funeral. He received the fateful call from one of the company's senior managers at headquarters in Auckland, New Zealand, where it was 11:00 p.m.

It *was* bad news. Laboratory tests had come back likely positive for *Clostridium botulinum* in some Fonterra whey protein concentrate known as WPC80. Thus was sparked a globally publicized multi-million dollar international recall.

"I began my career as a food technologist and although I knew botulism is hardly ever found in dairy, I knew we had to act," Spierings says. "Food safety must always be our number one priority. So the first thing I did was ask what products had been affected, which customers and which geographies. We then immediately informed our board of directors and the New Zealand Ministry of Primary Industries (MPI), which regulates food safety, and went public with our precautionary recall."

On Friday, August 2, Fonterra initiated a precautionary recall of 38 tons of its WPC80, advising the eight customers, including three food companies, two beverage companies, and three animal feed producers in Australia, China, Malaysia, New Zealand, Saudi Arabia, Thailand, and Vietnam, that had received the potentially affected ingredient.

Turn Back the Clock

The Fonterra WPC80 recall story actually begins in May 2012. On the last three days of WPC80 manufacture for the 2011/2012 New Zealand dairy season, the Fonterra whey manufacturing facility in Hautapu, New Zealand, produced three batches of WPC80 out of a rework process. This manufacture occurred from May 15 to 18, 2012, with the product reprocessed and packed on May 17, 18, and 22. The reprocessed WPC80 passed the standard, routine testing for compositional and food safety/pathogen requirements for whey powder.

Fonterra first identified a quality issue with this particular WPC80 in March 2013. At that time routine testing conducted at Fonterra's Darnum site in Australia identified high clostridia levels in finished product made for a customer.

Microbiology Testing

Immediately after the high clostridia levels were detected at its Darnum plant, Fonterra began an extensive process of microbiological testing at its research center in Palmerston North, New Zealand, to determine what type of *Clostridium* it was.

On May 8, 2013, a MALDI-TOF test (Matrix Assisted Laser Desorption/Ionization-Time of Flight), a sophisticated mass spectrometry technique, conducted at the research center indicated the clostridia were most likely *Clostridium sporogenes*, which isn't a food safety hazard but at high levels can cause food to spoil, but the findings were not definitive. The research center's further testing was unable to rule out the presence of *C. botulinum*. The definitive test for *C. botulinum*, a mouse bioassay, could only be conducted at two recognized testing facilities in New Zealand.

So on June 26, 2013, Fonterra commissioned AgResearch Limited, a New Zealand government-owned Crown Research Institute, to conduct a mouse bioassay test to confirm whether the identified strain was *C. sporogenes* or *C. botulinum*. On July 31, 2013 Fonterra received AgRe-

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search's test results, which identified the "potential presence" of *C. botulinum* in bacteria sourced from product containing the WPC80. The tests showed this risk was minute, but it was still a risk.

Thus, the midnight call to Spierings while he was in the Netherlands.

Tests in the U.S.

Subsequent to the precautionary recall, MPI commissioned testing at two U.S. labs that are accredited for *C. botulinum* testing—the CDC, Atlanta, Ga. and the National Veterinary Services Laboratory, Ames, Iowa.

Tests using a range of technologies were conducted in the labs and all definitively confirmed the recalled WPC80 contained a harmless strain of *C. sporogenes* and was clear of *C. botulinum*. As soon as clear and definitive test results were received, the MPI proactively released these results to the public on August 28, 2013—26 days after the recall was initiated.

Manufacturing Trace Back

The MPI documented its actions in response to the Fonterra WPC80 recall and on August 28 published a "Whey Protein Concentrate Incident Tracing and Verification Report" dated August 25. The 61-page report includes the following details.

- The dairy material for reworking was reconstituted, chilled, and then processed as usual. Equipment for reconstituting (rehydrating) dairy material had been decommissioned, so temporary (non-standard) equipment was introduced to facilitate this processing aspect.
- All equipment was subject to cleaning in place (CIP) prior to use and after each day's manufacture.
- Immediately prior to and following manufacture of the WPC80, the plant also manufactured a protein called hydrolysate. While there was common processing equipment used for both WPC80 and hydrolysate, the temporary equipment associated with the contaminated WPC80 was not used for the hydrolysate. This helped to identify the likely source of contamination.
- The rework was completed using manufacturing equipment common to the hydrolysate and fresh WPC80 manufacturing processes, with the exception of food grade flexi-hoses and the microfiltration line.
- The equipment operator's investigation concluded the cause was either within the product lines used to deliver the reconstituted product or within a microfiltration line.
- The data suggested either the reconstituted product line or the microfiltration line contained a protein deposit/biofilm. This is likely to have harbored clostridia spores and may not have received the full effect of CIP. The majority of the evidence pointed to the reconstituted product line being the cause of the problem.
- It was determined *Clostridia* contamination occurred during this reprocessing. To complete the reprocessing, an item of nonstandard equipment was used, namely a transfer pipe.
- Although standard cleaning procedures were followed, including those for the transfer pipe, subsequent analysis of the plant by the MPI shows the source of *Clostridia* was likely to have been this transfer pipe. The pipe has since been decommissioned.

Fonterra Reviews

On August 12, the Fonterra board of directors established the WPC80 Inquiry Committee, and charged them to oversee an independent review of the circumstances that led to the WPC80 recall and the subsequent chain of events.

Soon after initiating the precautionary recall, Spierings commissioned an in-house Operational Review to enable the cooperative to understand the cause of the contamination and evaluate how the business handled the incident and precautionary recall. The Operational Review team was also asked to make recommendations on how Fonterra could prevent an event like this from happening again.

Led by Maury Leyland, Fonterra's group director of strategy, the Operational Review team presented its findings and recommendations to Spierings on August 30. The Operational Review of Fonterra's WPC80 concluded that no single occurrence led to the precautionary recall and the events that ensued, and that no single issue was the sole contributor.

"The WPC80 incident was the result of a number of separate and unrelated events occurring in an unforeseen sequence," Leyland says. "One of those events was the decision to reprocess the original WPC80 and not downgrade the product, in combination with the use of an item of non-standard equipment, which was the cause of the contamination."

While the root cause of the contamination was an item of nonstandard equipment used in reprocessing the WPC80, a computer systems upgrade and lapses in escalation and communication to higher levels of management also contributed to the event, says Leyland.

"Actions have been taken to immediately address these issues," she says. "Specifically, in relation to the reprocessing of the WPC80 and use of nonstandard equipment, we have clarified our reprocessing procedures with our teams and these have also been embedded into our HACCP plans.

"In New Zealand each year Fonterra produces 2.3 million tons of high-quality dairy products from 17 billion liters of milk," Leyland says. "To achieve this we have world-class manufacturing facilities, quality systems, and robust testing regimes in place. This event stress tested all of them. Overall our systems worked well, while some aspects showed room for further improvement."

Government Reviews

The MPI and the New Zealand government are conducting WPC80 recall reviews. The Government Inquiry into the whey protein concentrate contamination incident has three parts divided into two tranches. Part A is an inquiry into how the potentially contaminated whey protein concentrate entered New Zealand and international markets, and how this was subsequently addressed. Parts B and C involve inquiries into regulatory and best practice requirements, and comparison of Part B's findings to similar matters in other comparable jurisdictions, respectively.

All recalled Fonterra WPC80 was accounted for or contained by the time MPI released its Tracing and Verification Report on August 28. That same day, MPI acting director-general Scott Gallacher issued a statement confirming that, based on testing and additional information, the identified batches of WPC80 and all recalled infant formula products containing this WPC80 were not contaminated with *C. botulinum* and posed no risks to consumers of contracting botulism.

To date, there have been no confirmed reports of illness as a result of any person or animal consuming this recalled WPC80 or any products that contained it. Moreover, there never was actually a botulism risk associated with the WPC80 to begin with.

MPI is undertaking a compliance investigation into the WPC80 incident to determine whether regulatory requirements under New Zealand's Food Act 1981 and Animal Products Act 1999 were met by all parties involved, or whether any parties may have committed any breaches or offences.

In-House Recommendations

Based on comprehensive findings, and to achieve the intended outcomes, the in-house Fonterra Operational Review recommended 20 actions which cover four key elements of the cooperative's business, namely people, products, systems, and response.

"The Operational Review concluded that Fonterra's quality and care systems in our manufacturing and testing are robust, and underpin our reputation for leadership in the global dairy trade," Leyland says. "Transparency of information, internally and externally—despite the lapses in information sharing and escalation noted in the review's findings—and commitment to public safety, were reflected throughout this event. Notwithstanding the shortcomings identified by the review, our staff, on most occasions, acted conscientiously on new information and generally sought to do the right thing.

"Although the initial likely identification of *C. botulinum* proved not to be a food safety risk, the significant impact of the recall stress-tested a great many systems across our company's business," she says. "Now we are using the lessons and improvements from this event to enable us to take a leadership position in product traceability and food safety and quality in the global food and dairy industries."

Spierings is quick to concur. "As a global leader in supplying dairy nutrition, I am confident that our action plan will make us even stronger," he says. "Fonterra is committed to providing high quality dairy products to our customers and to people around the world, and to putting food safety above everything else we do." ■

THERE'S MORE TO THE STORY...
go to December/January issue on www.foodquality.com and click on this article for expanded content.

Leake is a food safety consultant based in Wilmington, N.C. Reach her at LIleake@aol.com.

Botulism and Babies: It's Not About Formula

The possibility of getting infant botulism from infant formula is very rare, says Eric Johnson, ScD, a professor at the University of Wisconsin Department of Bacteriology. A respected scientist whose 30 years of research focuses on *Clostridium botulinum* and its toxins, Dr. Johnson has been providing expertise to Fonterra Cooperative Group relative to its whey protein concentrate recall.

"Infant botulism almost always comes from other sources, such as vegetables or dust," Dr. Johnson emphasizes. "There is only one reported case of infant botulism linked to consumption of infant formula in medical literature. In this case the result was inconclusive, with experts noting the illness might well have been caused by sources other than the infant formula."

C. botulinum is a spore-forming bacterium and the spores are highly resistant forms of the organism that are prevalent in nearly every region of the world. To grow, these bacteria require an oxygen-free environment that's warm and moist. *C. botulinum* bacteria are commonly found in soil, dust, and some marine environments, so most people are exposed to the spores likely on a daily basis.

Like plant seeds, spores can lie dormant for years. Spores are not threatening until they encounter an adequate environment for growth. The spores that germinate produce the deadly botulinum toxin, which is the most poisonous substance known.

Since *C. botulinum* is present in the environment, many foods do become contaminated with the spores. "Most of these foods are vegetables and associated foods that contact the soil," Dr. Johnson points out. "The number of spores in infant formula is either non-existent or extraordinarily few and so the likelihood of getting infant botulism from infant formula is extremely rare."

The number of spores required to cause infant botulism is not known, but based on honey studies it's thought to be as low as 10 spores on ingestion and up to 100 spores or more. "So in infant formula, the number of spores present is generally much lower than the dose required to lead to disease," Dr. Johnson says.

There are likely less than 150 cases of hospitalized infant botulism globally each year, but about 70 percent occur in the U.S., Dr. Johnson says. "That's probably because of the high incidence of the type of *C. botulinum* spores that cause infant botulism and the rigorous surveillance practices in place in this country."

The diagnosis for botulism is detecting the toxin. Since it's the toxin, not the organism, that is solely responsible for the disease, detection of the toxin is the only definitive proof.

The standard procedure for the detection of botulinum toxin is the mouse lethality assay. The test is based on an intraperitoneal injection into laboratory mice of sample diluted in phosphate buffer. If the sample contains toxin, the mice develop typical signs of botulism, including fuzzy hair, muscle weakness, and respiratory failure that manifests as a wasp-like narrowed waist.

"There are other assays being developed, including one in my lab in which neuronal cells are used to test for the toxin, but right now mouse assay is the only definitive test," Dr. Johnson says.

"The development of rapid new tests for inexpensive screening for spores could be beneficial to the food industry," he adds. —*L.L.*

Attitudes and Aptitudes Essential in Employee Selection

Careful pre-employment screening can ensure companies receive a good return on the investments they put into training new food safety hires | BY **TIM DONALD**

Pre-employment screening of job candidates is important to make certain that companies get the employees they want for food safety positions, according to experts in the fields of recruitment, evaluation, and resource development.

While candidates' experience and abilities will always be central to their aptitude for a given position, experts emphasize that the potential employee's attitudes, beliefs, and values can be equally important in determining whether a person has the "right fit" for a job.

"We look first of all for experience, and then we look at education secondarily, but we also try to get someone who understands the Costco culture," says Craig Wilson, vice president for food safety and quality assurance at Costco Wholesale in Issaquah, Wash. "We have a dynamic operating culture at Costco, and we need to have somebody who will fit into that."

Ascertaining the necessary skills, attitudes, and beliefs of candidates for food safety positions in the food industry often falls to recruitment or workforce development organizations. *Food Quality & Safety* spoke to several experts in these types of companies to explore what qualities are most important in finding the best candidates for these vital posts.

Determining Attitudes

Pre-employment screening is one part of a systematic approach to ensuring food safety, quality, and security, notes Preston Hicks, PhD, LPC, vice president of resource development and evaluation for the Global Food Protection Institute (GFPI) in Battle Creek, Mich. Training and education can provide a candidate with the skills necessary for a position, he says, but screening is key to determining whether that person has the correct intentions for use of those assets, as well as defining his or her unique learning path.

"At the front end, you try to ensure that the applicant has the sheer knowledge, skills, and abilities you need, or can fast acquire those. You try to create systems that provide quality training for that prospective employee before they even become an employee," Dr. Hicks says. "But when you talk about screening in food safety, it comes down to the person's intent. What does the person do with that knowledge, those attributes?"

Recruitment and workforce development firms have developed sophisticated software systems and testing regimens to help determine the attitudes of job candidates before food companies commit to hiring them for food safety positions, Dr. Hicks notes.

"These systems create a benefit for the company on the front end, so they don't spend money on training and end up not getting a good return on their investment," he says.

One such company is Educational Data Systems Inc. (EDSI), in Dearborn, Mich. EDSI performs candidate screening and recruiting initiatives for client companies in food and agriculture as well as other fields.

"We usually start with an assessment of what the customer's needs are,"

says Kenneth Mall, managing director for EDSI. "We try to define what kinds of skills the company is looking for, but also what type of person would be successful in their environment. When we start looking at candidates, we want to assess not only what skills they bring, but also their personality profile."

To accomplish this, EDSI uses a range of tests, depending on the job and the company's needs. The screening battery may include an aptitude assessment (Bennett or Ramsay), a basic math and reading level evaluation such as the Tests of Adult Basic Skills (TABE), and a predictive index to establish a personality profile.

Predicting Behavior

Another firm involved in pre-employment screening is MuRF Systems, a consultancy in Amarillo, Texas, that assists companies with workplace relationship issues. Jody N. Holland, owner and president of MuRF Systems, says one of the aims of screening is to try to predict potential employees' behavior before committing to a hire.

"Most people are fired because they don't have the right personal makeup to be in that position; they don't fit," Holland says. "Companies normally hire people based on skill, not fit, but both are important. We really should hire based on fit *and* skill."

Holland and his colleagues have designed psychometric testing to help determine fit and predict a candidate's behavior in the workplace. He gives the example of hiring a manager to oversee quality control personnel.

"You need to know that you can predict the way that person is going to behave in managing, the way they are going to inspect everything that their food safety people have done, so that nothing gets missed," Holland explains. "The problem a lot of organizations have is, they hire somebody who went to school for this type of position, so they're educated, but they don't have the behavioral makeup to say 'I'm going to pay attention to detail, I'm going to verify and double-verify, and make sure that everything stays exactly on track.' And that is what they need for success."

"Generally, I like to see that the certification was updated within the candidate's last position."

—WILLIAM S. MAYWOOD,
owner, Careers in Sanitation

Psychometric testing can increase the odds of choosing the right person for such a position, Holland says. He cites a study by researchers at Harvard Business School suggesting that the traditional hiring process results in a 15 percent chance of making the right decision, while use of

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behavioral interviewing, psychometric testing, and background checks boosts the odds of a good hire by up to 60 percent.

The first step in finding a good candidate, he says, is to create a psychological profile of someone already employed at the company who has demonstrated that he or she is the right fit for the job in question.

"Within a plant, say you have one supervisor who has been phenomenal, but he wants to retire," Holland explains. "We test him with a psychometric test that takes about 20 minutes. We measure his behavioral makeup, which predicts his behavior patterns. And we measure his work-type interest, which determines what he pays

"We want to assess not only what skills they bring, but also their personality profile."

—**KENNETH MALL**,
managing director, EDSI

attention to. Then we can measure other people against that psychological profile. The process of matching candidates to that established profile is relatively easy."

His recommendation is to look for a 70 percent or higher match between the existing worker's profile and the job applicant's profile. "Then you can modify the rest of those behavior patterns in house," Holland says. "You almost never get a 100 percent match."

The psychometric tests developed, validated, and used by MuRF are based on previous research such as William Marston's work on behavior prediction (he developed the DISC assessment: Dominance, inducement, submission, compliance) and John Holland's profiles of work-type interest, Holland says.

"The goal is you want to predict what a person will be like at work, before you put them in that position," he adds. "We look at our service as eHarmony.com for employers."

Online Matching

A different approach to online matching is offered by Careers in Sanitation, based

"There have to be protocols that people pass to get these jobs in the food industry."

—**PRESTON HICKS**,
VP of resource development and evaluation, GFPI

in Chalfont, Pa. CareersinSanitation.com is an online job board, similar to Monster.com or CareerBuilder.com, specializing in recruitment for food safety and sanitation personnel.

"It's a very niched job board," says William S. Maywood, III, owner of Careers in Sanitation. "When companies have an opening, they can go online and post their job in front of individuals who are searching for a job in sanitation or food safety. It allows employers to directly connect with individuals who already have a knowledge of the industry or who are seeking to come into the industry—whether a college grad or someone in a production job who wants to get more into the quality end."

The company makes its job-board services known to students at academic institutions that offer food microbiology and food safety programs, and it promotes to employers the fact that it holds a database of active job seekers, Maywood says. The company also contracts to provide screening and recruitment services for employers.

In screening for candidates, the criteria vary depending on what a specific company is looking for. "Many companies are concerned with making sure their managers have an understanding of the Hazard Analysis and Critical Control Points (HACCP) program," he says, "but in the past year or more there has been increased interest in the BRC Global Standards; companies are moving toward the BRC standard, and they want their managers to have that background."

Also important is how recently a certification has been obtained.

"We want to make sure that a candidate's background is relevant and up to date," Maywood says. "We see a lot of candidates who say went through HACCP certification in 2000. Well, in the past 13 years a lot has changed–not to mention in the past 13 months. Generally, I like to see that the certification was updated within the candidate's last position."

Usually, entry-level candidates finishing a college degree program will not have a company's desired certification, but if the right fit is found, the company may sponsor a candidate to obtain the certificate, Maywood says. "That's often a good tactic for the employer because it shows the person coming into the job that the company is looking for the best in their future," he says.

In the age of social media, Maywood says he instructs job seekers to "scrub" their Facebook and other social media pages when seeking jobs. He also tells employers that they cannot ask potential employees for usernames and passwords for their personal social media accounts as a condition for employment.

"The question comes up all the time: Is this legal? The answer is No, not unless it's a government or law enforcement position, and even that varies by state. So we tell everyone, don't ask for it," he says.

Component of Risk Management

Pre-employment screening for food safety workers is an important component of risk management for companies, notes Dr. Hicks of GFPI.

"With the globalization of the food industry, we have to be vigilant in who we hire and how we train," Dr. Hicks says. "Screening has to be rigorous. There have to be protocols that people pass to get these jobs in the food industry."

In a way, everyone involved in the food industry is involved in food safety, he adds. In addition to screening, proper employee training is needed to ensure that an integrated food system provides safe food for consumers.

"A person who's well trained is a security measure," Dr. Hicks says. "Their knowledge, skills, and abilities allow them to see when something is not right. If we are not training people properly, they don't know what to look for, don't know when a deviation warrants attention, or stopping a line, or pulling a product. Quality trained people, both on the regulatory side and in the private sector, are absolutely critical to our line of defense for food safety." ■

Donald is a veteran journalist with extensive experience covering a variety of industries. Reach him at timdonald2020@gmail.com.

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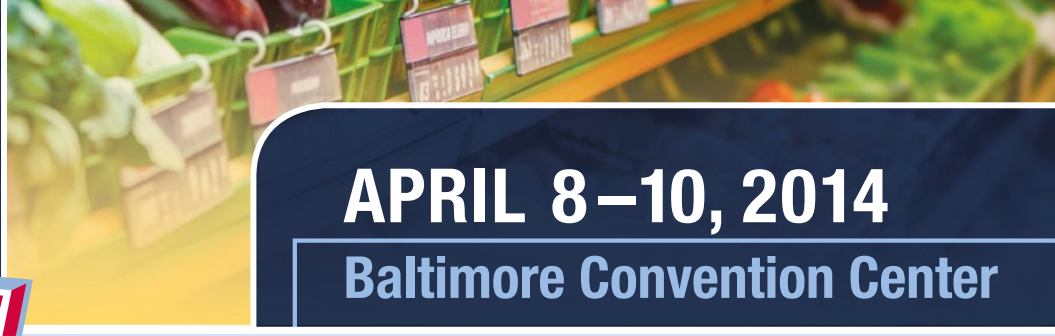

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Avoid Stagnancy: Only Settle for Dynamic Pest Programs

Improving a program based on pest activity and trends can make all the difference between a successful pest management plan and an inefficient one | BY **ZIA SIDDIQI, PHD, BCE**

Editor's Note: *This is final installment in a five-part series of articles that provide a practical approach to pest control topics.*

Since pest activity constantly fluctuates based on facility conditions and seasonality, stagnant is the last word by which you want to describe the pest management program at your facility. It should instead be dynamic and change as necessary over time according to pest activity and trends. But how do you know when your pest management program needs to be altered in a small or large way?

The key is to work with a pest management company whose pest professionals understand the science behind pests and the activity they exhibit throughout the year. Here are a few factors to look for to ensure you are signing a contract with a company that truly understands how to develop the best pest management program for your unique facility.

Audit-Ready Documentation

In the food manufacturing world, a company's bottom line can hinge on the score it receives on its food safety audits. Documentation of the pest management program is vital to the pest control portion of a food safety audit, which can account for up to 20 percent of the final score. Consequently, your pest management company should follow strict protocols in regard to documentation to ensure your logs and reports are audit-ready at any time. All documents should be housed onsite at your facility and should include pest treatment service reports, pest monitoring logs, corrective action reports, trend analyses, and pesticide usage logs.

> The last thing you need is for your facility to be left behind with outdated methods.

Along with serving an important role during the food safety audit, documentation helps the pest management professional monitor pest activity over time. When the pest management professional notices a change in pest activity trends, he or she can confirm that certain elements of your pest management program should be adjusted accordingly. Without this collection of data and documentation, he or she would not be able to show hard proof as to why the changes in the program should be made and, unfortunately, may not even be able to recognize a change should be made in the first place.

Periodic Visits

In addition to strict documentation protocols, look for a pest management company that offers periodic check-ins. Those check-ins should ideally be performed by one of your pest management professional's supervisors.

These visits will allow a fresh set of eyes to take a look at your facility's current pest situation, reevaluating the components of the pest management program. Furthermore, the visits will provide added confirmation that the pest management professional who services your facility is following company and industry protocols while treating your facility. In the case that any discrepancies are realized during these visits, you would then find yourself with an opportunity to remediate the situation and work with the pest management professional on altering the program as needed.

Annual Facility Assessment

Now that we've discussed documentation protocols for every service, as well as periodic supervisor visits, we can cover a meeting that should take place one time per year: The annual facility assessment.

During the annual facility assessment, the pest management provider will review several components of your pest management program to identify chronic issues your facility faced over the course of the previous year. These issues typically become apparent after the provider takes a look at the documentation that was completed at the end of every service visit, the pest activity trends analysis, and the evaluations from the periodic visits conducted by the pest professional's supervisor.

In addition, the provider may ask questions about the modifications you made in the last year both inside and outside the facility—did you install any new equipment, experience any damage to your building, or enforce any new procedures for staff? Chances are that you did make some changes, which means your pest management provider may need to take a modified approach to your situation and create a new strategy as a result.

Scientific Research & Technological Advances

Adjustments to pest management programs are largely influenced by scientific research and the advanced technology that is developed as a result. For example, stored product pest infestations can sometimes get out of hand due to the pests' rate of reproduction. Past scientific studies have led to new technology that prevents reproduction from happening in the first place. Pest control companies like Orkin now offer mating disruption pheromone dispensers, which allow for targeted pest management by confusing the insects from locating a mate. Thanks to this kind of scientific research, pest management methods for the food processing industry—and others—are more effective than ever. The last thing you need is for your facility to be left behind with outdated methods, so ensure the pest management provider stays abreast of the latest scientific research and uses the latest technology.

By finding a pest management company that fits this criteria, you will succeed in creating a partnership that leads to an effective pest control program. No matter what changes in pest activity will come along, you can trust your pest management professional will take the right approach to adjust your program accordingly and help protect your facility from an infestation in the long term. ■

Dr. Siddiqi is director of quality systems for Orkin, LLC. A board certified entomologist with more than 30 years in the industry, he is an acknowledged leader in the field of pest management. Dr. Siddiqi can be reached at zsiddiqi@orkin.com.

Testing

SEAFOOD

Vibrios and Human Health

Testing new depuration protocols to reduce the rate of *Vibrio*-related illnesses from oysters

BY **COVA ARIAS, PHD,** AND **JACQUE KOCHAK**

Most people can consume oysters by the dozens without ill effect, but people with liver disorders, diabetes, and immune-compromising conditions such as HIV/AIDS are at risk for the deadly vibriosis illness caused by a species of *Vibrio*. Individuals who take prescribed medication to decrease stomach acid or who have had gastric surgery are also at risk.

Vibrio vulnificus, a gram-negative bacteria that occurs naturally, especially in brackish, warm coastal Gulf of Mexico waters, causes a particularly horrific illness in vulnerable individuals—and the mortality rate hovers at 50 percent. Some 95 percent of all seafood-related deaths in the U.S. are caused by *V. vulnificus*, and the CDC reports that from 1996 till 2006, *Vibrio* infections increased by 78 percent.

The obvious solution to the problem would seem to be educating at-risk oyster eaters about the danger they're courting. The Interstate Shellfish Sanitation Conference—a coalition of shellfish industry members and state and federal regulatory agencies—launched an expensive information campaign aimed at doctors and restaurants with the idea of educating high-risk individuals about the dangers of eating raw or undercooked oysters.

It didn't work. Apparently, those who love the briny taste of raw live oysters are willing to take the risk.

In 2009, FDA proposed requiring all oyster producers to use a form of Post Harvest Processing (PHP) to sterilize raw oysters. The seafood industry pushed back, insisting that requiring PHP processes would drive many seafood companies out of business. That warning is not unrealistic because oyster harvesters are already under siege as a result of man's degradation of the Gulf coastal environment and scourges like the oyster drill, a carnivorous marine snail that drills a hole in an oyster's shell and sucks out the sweet innards.

Most oyster harvesters are small family operations, and they've already been decimated by oil spills in the Gulf. The nation's richest oyster grounds have also been affected by a series of hurricanes lashing the region and flooding from the Mississippi River, which flushed a torrent of fresh water into the northern Gulf, reducing salinity. More recently, the Deepwater Horizon oil spill tainted the brand name "Gulf Seafood," despite all the testing conducted by state and federal agencies that deemed seafood from the affected areas safe.

The FDA's plan would have required all oysters harvested from the Gulf of Mexico between May and October to be processed. PHP, however, not only kills oysters—changing their taste and texture—it is expensive for small operations. Most don't have the necessary capital to buy the equipment necessary to meet the proposed FDA regulations.

Avery Bates, vice president of the Organized Seafood Association-Alabama, told the Associated Press that two-thirds of Alabama's 50 "mom-and-pop" oyster shops would close because of the costs associated with processing the oysters.

Is there a way to make eating oysters safer without decimating a struggling mom-and-pop oyster industry? Unexpectedly, research conducted in my lab at Auburn University could become central to the debate.

Depuration

Since 2007, Auburn has been studying a post-harvest process called depuration to eliminate *Vibrio vulnificus* from Gulf oysters. Depuration involves transferring shellfish from polluted waters to a controlled, cleaner aquatic environment, allowing then to "open" and eliminate contaminants themselves, thus reducing bacteria to low levels.

Mollusk depuration is common in Europe, where the process is used to elim-

inate microbes that proliferate in waters contaminated by fecal waste.

In the U.S., depuration systems must be approved by the FDA and are used only in Massachusetts (clams), Maine (clams and oysters), and Florida (clams). These depuration systems are utilized only in fecal-contaminated waters because depuration of pathogens that occur naturally, such as vibrios, has proven challenging.

Several studies have shown depuration's potential for eliminating *V. vulnificus*. I did my undergraduate work with *V. vulnificus* in Spain, where the microbe is a problem for eel farmers but not a food safety issue. I realized depuration might be the only way to control *V. vulnificus* during summer months when it's more prevalent, while also keeping oysters alive for raw consumption.

The research started out by constructing a flow-through tank system using seawater pumped in from the Gulf. The idea was that water flow would be uninterrupted and sufficient to remove feces and pseudo feces as well as prevent recontamination. Flow rate was maintained at 11 liter per minute for six days, and salinity and temperature were measured twice a day. *V. vulnificus* numbers in the oysters were enumerated at day zero, one, three, and six using the FDA Most Probable Number procedure.

We found depuration was successful—but only part of the time. Out of 11 depuration trials run in 2008 to 2009 using naturally infected oysters, we observed significant *V. vulnificus* reduction in only six.

During these preliminary trials, we modified some parameters to favor removal of the microbe while still maintaining optimum physiological activity of the oysters with salinity, temperature, and dissolved oxygen being the most significant parameters. For example, we tried cooling the incoming water to 15 degrees Celsius (59 degrees Fahrenheit) during depuration without observing a significant decrease in *V. vulnificus* numbers.

We also increased the water-flow rate and saw total clearance of *V. vulnificus* in oysters within six days. Unfortunately, this result could not be repeated consistently. All the oysters were collected from beds off Dauphin Island, a barrier island at the mouth of Mobile Bay. Why, we asked, was there such a high variability in depuration efficacy when oysters were collected from the same physical location with only a few months difference?

The answer appeared to be elegant in its simplicity. There was little variation in water temperature in our trials using seawater, but salinity fluctuated between 9.5 parts per thousand (ppt) and 30.1 ppt. Remember, the northern part of the Gulf of Mexico is really a giant, salty estuary fed by the Mobile and Mississippi Rivers and whipped by storms that regularly dump fresh water into the ocean. Salinity

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can drop from 20 ppt to 0 ppt in less than a day.

V. vulnificus thrives in brackish, but not too salty, water and the main difference in *V. vulnificus* numbers between the Atlantic Coast and the Gulf Coast during the warm summer months can be attributed to differences in salinity. Since we were using pumped-in seawater, we tried adding a brine solution to the water to keep salinity high. Adding brine to incoming saltwater is too expensive, however, to provide a long-term solution for oyster harvesters.

So we tried using artificial seawater instead, continuously circulating in the tank with a UV light sterilizer and an ammonia removal media filter to get rid of the toxic ammonia excreted by oysters as a waste product. We set up three tanks with different salinity levels for comparison and then went to work. For a post-harvest method to be approved by FDA, a 3-log difference has to be demonstrated. For example, 13,000 colony-forming units (CFUs) per gram of oysters would have to be brought down to less than 30. The higher the salinity we observed, the lower the number of CFUs.

The concept was then needed to prove to work consistently. We carried out four trials in 2012, using different salinities (15, 25, and 35 ppt). Our data showed that when salinity was at 35 ppt, the numbers of *V. vulnificus* decreased by at least three orders of magnitude in two (out of four) trials. Depuration at this salinity was able to reduce *V. vulnificus* levels below the FDA requirement of less than 30 most probable number per gram. Oysters tolerated the depuration conditions with very low mortality (less than 1 percent), although their condition index decreased during depuration (14 days); oysters were not fed during that time, but this is something that we can change in the future. In addition, depuration was effective at day 10, and prolonged times did not increase depuration efficacy. Hence, high salinity depuration is a promising method to reduce *V. vulnificus* in oysters while maintaining a live, fresh product.

Because depurated oysters are still alive, the taste differs only because they are slightly saltier. As noted, FDA-approved post-harvest techniques—such as freezing, heat-cool pasteurization, exposure to high hydrostatic pressure, and irradiation—kill the oyster and change the taste and texture, except for rarely used irradiation.

Cold Shock

The Gulf Oyster Industry Council estimates that only 10 percent of oysters currently undergo PHP, and oystermen usually use refrigeration to preserve live oysters. That is why a major focus of my lab also has been "cold shock," the response of bacteria to cold. What mechanisms do *V. vulnificus* possess allowing adaptation to cold, and what risk does this pose to consumers?

The optimal temperature for *V. vulnificus* is 35 degrees Celsius (95 degrees Fahrenheit), not uncommon during summer on the Gulf coast. Most of these oystermen have small boats without refrigeration on board, so they go out for a short time and return to refrigerate their catch.

To study cold shock in *V. vulnificus*, we created a microarray to evaluate the expression of every one of *V. vulnificus*' 4,488 genes at three different temperatures. We confirmed that when taking oysters down to 7 degrees Celsius (44.6 degrees Fahrenheit), the microbes' proliferation is stopped. In fact, something major happens around 10 degrees Celsius (50 degrees Fahrenheit). That seems to be the threshold temperature where genes start turning on and the microbe gets into gear to handle cold.

When we lowered the temperature to 4 degrees Celsius (39.2 degrees Fahrenheit) instead of 7 degrees Celsius, the bacteria were no longer metabolically active, so our recommendation would be to keep oysters at 4 degrees Celsius.

We found, however, that if you take oysters down to 15 degrees Celsius (59 degrees Fahrenheit), leave them for several hours and then go down to 7 degrees Celsius, you can have problems. In that gap between 7 degrees Celsius and 15 degrees Celsius, the bacteria not only continue to grow, they adapt to the cold and can even proliferate.

HHP

Although oystermen who opt for a PHP method are in a decided minority, one of the most popular PHP methods is hydrostatic high-pressure (HHP) treatment. At the behest of a commercial seafood processor and distributor, we compared HHP-treated oysters to flash-frozen oysters and oysters kept raw at 4 degrees Celsius. We repeated the testing in the winter, the summer, and the fall.

HHP-treated oysters are supposed to have a shelf life of 21 days, and we found HHP treatment indeed eliminated the majority of human pathogens in oysters, at first reducing them to non-detectable levels. The bacteria that remained adapted rapidly and thrived under refrigeration, however, and after one week the HHP-treated oysters had more bacteria than the week-old raw oysters. In fact, I have rarely seen bacteria levels so high—but the good news is that oysters aren't kept that long. HHP-treated oysters are certainly very safe, but they don't seem to have a very long shelf life.

Another species of *Vibrio*, *V. parahaemolyticus*, infects oysters in the Gulf as well as in the cooler northern waters of the Pacific, from California to Alaska. Depending on the year, and on the salinity and temperature of the water, there may be more *V. parahaemolyticus* than *V. vulnificus* in oysters from Alabama's Dauphin Island.

The CDC estimates vibriosis caused by *V. parahaemolyticus* causes some 4,500 illnesses annually. We have run a few depuration trials to see if increased salinity affects *V. parahaemolyticus*. As expected, high salinity depuration was not as effective in removing *V. parahaemolyticus* as it was in reducing *V. vulnificus* but an average of 2-log reduction was observed, which makes us optimistic about using depuration to reduce both pathogens.

Development of a high-salinity depuration system to reduce pathogenic vibrios in Gulf oysters will promote a struggling industry and reassure millions of oyster-eaters that they can eat the raw delicacy with confidence. There is regional interest in developing intensive oyster aquaculture, so oyster farmers also would benefit tremendously. Most importantly, a reliable, economical oyster depuration system would save lives. ■

Dr. Arias is a professor in fisheries and allied aquacultures at Auburn University and part of the multidisciplinary Auburn University Food Systems Initiative, which recently was awarded an FDA grant to help develop a food safety training program for food inspectors. Reach Dr. Arias at ariascr@auburn.edu. **Kochak** is the communications specialist at Auburn University Food Systems Institute.

Quality

PRODUCT RECALLS

Increasing Risk and Regulation Drives Change in Recall Management

Best practices for creating and testing a response plan in order to minimize damage during crisis situations

BY **MELANIE NEUMANN, JD, MS**

What does the globalization of the food supply, the increase in co-manufacturing and private label manufacturing, advances in technology, increasing consumer sophistication and demand for information, and new regulations all have in common? Each individually, and collectively, contribute to the risk of experiencing a product recall.

More than ever are we seeing lawmakers, regulators, consumers, and the media more focused on food safety. Several outbreaks of foodborne illness in recent years have identified new risks and have put food safety in the spotlight. The changing consumption patterns, global sourcing, evolving food-safety science, and the identification of new risks all contribute to the shifting food-safety landscape.

The science of food safety is continually evolving: New laboratory tests, improvements in genetic testing, and a greater fidelity of epidemiology have resulted in better capacity to detect and identify foodborne pathogens, and to link illnesses with specific food products. The vigilance of both mainstream and social media, along with consumer's capacity to damage a brand has made it all the more important to maintain a robust food safety program. This includes a well-developed recall and crisis management plan that adapts to change whether it is regulatory, science, or consumer driven.

The signing of the Food Safety Modernization Act (FSMA) by the U.S. President in January 2011 is the most sweeping overhaul of the food-safety system in the U.S. since the Food, Drug, and Cosmetic Act of 1938. While FSMA has already delivered broad-sweeping changes through several proposed rules that have been released to date, this article will focus on the impact of FSMA on recall plans and the importance of effective recall management.

Regulatory Agencies and Applicable Recall Regulations

FDA and the FSMA. The FSMA specifically provides the FDA with mandatory recall authority, complete with the power to order a firm to cease distribution and recall a product "if the Secretary determines,

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based on information gathered through the reportable food registry under section 417 or through any other means, that there is a reasonable probability that an article of food...is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals."

What does this mean exactly?

First, this new authority simply means that FDA has the power to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to do so by FDA. The reality of a company refusing this request is very unlikely thus we won't see many truly "mandatory" recalls. However, if mandated, FDA can issue an order requiring the firm to immediately cease distribution of the affected product and immediately notify all persons who manufacture, process, pack, transport, distribute, receive, hold, or import and sell the affected product of the recall and to immediately cease distribution.

Second, there is one phrase in Section 417 that packs a big punch by way of impact on the scope of records FDA is entitled to review and copy in relation to a recall investigation. That is the "reasonable probability" standard. Prior to FSMA, FDA needed "credible evidence" of a situation that could cause serious adverse health consequence or death. Now this bar has been lowered—significantly—to only needing a "reasonable probability." This expands FDA's ability to seek and obtain records to ones previously off limits pre-FSMA. The bar may be lower, but the stakes are higher if you are not properly documenting and retaining required documents pursuant to the record retention requirements under FSMA's new rules.

FDA provides an industry guidance document located on its website that outlines the major considerations and components of a recall. This document includes the key pieces of information needed and execution steps expected by the agency in the FDA Recall Industry.

USDA Food Safety Inspection Service (FSIS). Different from FDA's mandatory recall authority, under USDA/FSIS regulation, it is a firm's decision to voluntarily recall a product. However, FSIS coordinates with the firm to ensure it has properly identified and removed the recalled product from commerce by verifying the effectiveness of the firm's recall activities. Companies under FSIS jurisdiction who find themselves in a recall are required to notify their local FSIS District Office personnel within 24 hours when they learn or determine that adulterated or misbranded product has entered commerce. FSIS also requires firms to prepare and maintain recall procedures detailing how to conduct and execute a recall, and affords FSIS the right to review and copy records that may relate to a recall.

USDA provides guidance on how to manage a USDA recall in its Directive 8080.1 Rev. 7 document, which can be found on its website.

Both agencies notify the public about product recalls through public press release announcements, and email alerts sent by each agency to subscribers, such as the FDA Recalls, Market Withdrawals, and Safety Alerts.

Preparation is Key

Understanding the regulations and expectations by the agency that governs you isn't enough to truly be "ready" to successfully handle a recall. Companies must focus on preparation rather than reaction. By focusing on the following best-in-class preparation tactics, companies can better prepare themselves to tackle a recall and come out on top. The suggested tactics are as follows.

Create a Written Recall Plan. Both FDA and FSIS require written recall plans with specific elements, but what additional content should be in an effective recall plan? In my years of experience, the following elements are the keys of a robust recall plan that possesses a high probability of executing a successful recall:

- Corporate policy statement—commitment to food safety and quality and placing consumer health and safety at the forefront of all decisions;
- Cleary defined roles and responsibilities;
- Incident identification, investigation, and escalation process;
- Health hazard evaluation process;
- Communications plan and procedures; and
- Training and testing through simulations.

Develop a Toolbox. Time is of the essence in a recall or other food related crisis. Sitting down in the midst of an actual crisis is *not* the time to start putting pen to paper for the very first time. Avoid the rush of writing content for a press release or researching appropriate health risk statements by planning in advance. Take the time now—in a time of calm not chaos—to prepare as much of this information in advance to save precious time during an actual incident. Good "tools" to develop and have in your toolbox include:

- Templates—press releases, FAQs for your call center and website, customer letters, and agency communications;
- Checklists—recall action items and meeting logs; and
- Contact Lists—internal recall team and backups and external expert resources.

Test Your Plan Through Simulations. The importance of training and testing your recall plan cannot be emphasized enough. The most effective way adults learn today is by practical, hands-on learning. So kick the tires of your plan, test your systems, and challenge your people! Do not make these simulation scenarios easy just to check the box. Your organization will not grow and improve unless you challenge the people, process, and technology that you rely on to successfully execute a recall.

Thus, companies should conduct both announced and unannounced recalls. Consider including your customers in the simulation by selecting a finished product of one of your major customers. This shows your commitment to food safety and the protection of your customer's brand, and often your customer requires you to conduct a simulation using one of their products anyways.

Do not be afraid to challenge your traceability capabilities by selecting an ingredient that is used in several different finished products you produce to get a realistic assessment of your track and trace strengths and weaknesses. Don't stop at the trace. Continue your simulation through to its natural conclusion which is the need to prepare an effective and appropriate communication plan for each audience impacted by the recall (e.g. actually draft a consumer level press release and/or a customer recall notification letter). We have seen many recalls remain in the media spotlight due to ineffective PR and communications strategies. Avoid the unwanted spotlight, and test in advance. This is not the time to take risks.

Your organization will not grow and improve unless you challenge the people, process, and technology that you rely on to successfully execute a recall.

Call in the Pros

One of the best things you can do is "know what you don't know" then call in the professionals. Use experts in areas where your organization may not have the bench strength needed in a particular food safety or recall incident. It's important to recognize that experts are not only people with specific knowledge in a certain area, but also technology solutions providers and testing and equipment manufacturers.

Identify experts, call centers (for surges in call volume), and laboratories in advance. Take the time to educate these service providers on your business, products, and risk tolerance before an actual crisis instead of during one when every minute becomes a precious commodity you cannot afford to waste. Conduct all necessary vendor approval steps and establish these resources as fully vetted sup-

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pliers/vendors before you need to "turn on the light switch" and call them into action in an actual or threatened crisis situation.

It is best practice to have the following resources established and in your network of vendor partners ready, willing, and able to assist if you need them:

- Microbiologists,
- Medical experts,
- Toxicologists,
- Epidemiologists,
- Public Relations Firms,
- Attorneys,
- Laboratories,
- Call Centers, and
- Product Retrieval Firms.

Leverage Technology

In this era of heighted consumer awareness and sensitivities to allergens and country of origin information, as well as a global supply chain, sourcing from so many different suppliers from all over the globe delivers an ever-increasing amount of risk. This fact is difficult to ignore as we have seen many recent recalls caused by suppliers sending adulterated ingredients to a finished product manufacturer. Using technology to help manage this risk is a good decision to not only ensure compliance with regulations, but more importantly to ensure brand protection.

Some areas where food companies have best leveraged technology to mitigate the risk of a recall are as follows.

Inventory/Production Systems. Being able to quickly identify affected products subject to a recall is imperative. To facilitate this, it is of vital importance to document and retain relevant production information including date of receipt of ingredients and utilization in finished product(s) lot and/or batch codes, and distribution records. The use of electronic systems rather than manual records helps ensure this information is quickly accessible and accurately identifies the affected scope of the products to be recalled.

Supplier Compliance Systems. If companies are assessing and monitoring their supplier risk appropriately, they are asking suppliers to provide a lot of information—from food safety plans and allergen control programs to certificates of insurance and indemnification agreements. The days are numbered where industry can continue managing records manually. The more companies can leverage technology to manage its risk the better protected a company will be. Technology decreases the risk for human error and manages a plethora of critical data elements electronically to confirm suppliers are complying with expectations and risks are controlled, eliminating manually-kept processes.

Complaint Management Systems. Customer Relationship Management (CRM) systems are effective risk management tools in that these systems document as well as trend complaint data over time. CRM systems typically share similar features such as the ability to electronically and automatically identify trends by programming specific "triggers" in the system. For example, a company may determine that three complaints on the same product/same lot code for the same or similar reason warrants escalation to the food safety team to further investigate. CRM systems also allow users to auto-notify preselected people in the company that there may be an issue that warrants further attention. It also allows for effective data capture and documentation management to show that each complaint was attended to, investigated as appropriate, and resolved in some manner. Attempting to do all of this manually is ripe for the risk that a critical complaint or trends will be missed and goes unreported, which could lead to a recall, or one much larger in scope then if the issue was identified and investigated right away.

These systems also help achieve a key best practice: Documentation. In the eyes of the agencies as well as the media, plaintiff's attorneys and consumers—if it isn't documented, it didn't happen. Using technology verses manual records heightens the odds that all key information is documented on a consistent basis.

Conclusion

Having well-defined recall procedures and an active, well-trained recall team are the first steps to better recall management. Coupled with combining this strategy with technology solutions and best practices helps food companies efficiently and knowledgably manage recalls and, more importantly, reduces the consuming public to exposure of potentially dangerous products. The benefits of an organized recall program include organizational efficiency, brand protection and, most importantly, public health and safety. ■

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REFERENCES FURNISHED UPON REQUEST

Food Recalls: How Does the GFSI Fit?

Exploring whether there is a connection between GFSI-certification and reduction in food recalls

BY **SUSAN MOYERS, PHD, MPH**

An overarching goal of the Global Food Safety Initiative (GFSI) is to increase consumer confidence in the safety of food products. The GFSI undertaking has evolved in a changing, dynamic marketplace, with complexities that include the increasingly global supply chain, changing culinary preferences, changing guidance by nutrition authorities, new dietary ingredients and formulations, extended shelf life, emerging pathogens, advances in packaging materials, and other factors. In the aggregate, these factors yield a hugely complex supply of food and beverage products, with more and varied products in the marketplace than ever before. Looking at the dynamics of the food industry, the Grocery Manufacturers Association (GMA) in 2011 predicted that the frequency and impact of recalls will continue to rise.

The raw material supply chain in particular has triggered many widely-publicized recalls. One recall by a single supplier, or for a single ingredient, can exponentially impact a downstream customers and consumers, generate major costs to industry, and threaten brand protection long term.

GFSI-compliant audit schemes generally mandate higher standards than are required by individual governments, even governments in developed countries. Facilities which pass GFSI-benchmarked audits can claim adherence to these high safety standards, and are thus said to also gain market edge with industry-customers, particularly retailers.

Because GFSI-certified facilities use rigorous prevention programs, the question arises—do these facilities have fewer recalls in the U.S. compared to those non-GFSI certified? With this question as a backdrop, the October/November 2012 issue of *Food Quality & Safety* included a review of public reports involving recalls and involvement of GFSI-certified operations. This article is the one-year follow up.

Methods

Information was extracted from the U.S. FDA list of "Recalls, Market Withdrawals, and Safety Alerts" and its weekly "Enforcement Reports," as well as from the USDA's Food Safety and Inspection Service list of "Recalls and Alerts" for the period between May 1, 2012 and April 30, 2013. Dietary supplements were included in the review; veterinary products were not included. The publicly-available data provided for human food and dietary supplements included the number of recalls, recalling firms, dates and reasons for recalls, and in many cases, the amount of product recalled. For purposes of compiling the review, recalls were organized by date and reason. For example, a facility with a *Listeria* finding might have recalled one product or multiple products on a given date; the recall was counted once, even though more than one product might have been recalled by that facility on that date for the stated reason.

For each distinct recall, we queried the public databases of GFSI-scheme owners to determine whether the recalling company and/or reported manufacturing facility/farm were certified on the date(s) of the recall. Of the nine GFSI-benchmarked audit schemes, we found seven in use for certification in the U.S. during the period studied. The schemes are: British Retail Consortium (BRC), London, England; Safe Quality Food Institute (SQF), Arlington, Va., U.S.; Food Safety System Certification (FSSC) 22000, Gorinchem, The Netherlands; PrimusGFS, Santa Maria, Calif., U.S.; International Features Standards (IFS), Berlin, Germany; Global Aquaculture Alliance (GAA), St. Louis, Mo., U.S.; and GlobalGAP, Cologne, Germany.

Some facilities issuing recalls were also certified by schemes not currently benchmarked by GSFI. Other factors to point out include participants in GlobalGAP have a privacy option to restrict data from a public search; and IFS does not publicly list certified sites. As a result, in some recalls, the facility/company websites were accessed and/or personal communication was made to obtain certification status at time of product recall. There were a handful of facilities where certification data were missing.

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Results

There were 743 recall notices reported from the USDA and FDA in the U.S. and Puerto Rico, between May 1, 2012 and April 30, 2013. This included 654 from FDA and 89 from USDA. The recalls include finished products as well as recalls at the ingredient level where more than one finished product and/or manufacturer was affected by the same safety event(s).

The most common reason for recall was mislabeling or not labeling allergens, 27 percent of all recalls; this increases to 29 percent if recalls for undeclared sulfites are included. Although allergens remain the top reason for recalls, as they were in 2011 to2012 review, their overall percentage year-over-year dropped. Allergens are followed by recalls for *Salmonella* at 19 percent; *Listeria monocytogenes* at 14 percent; and foreign material at 9 percent. The latter reflects mostly metal or plastic found in the product. Compared to the prior period, the percentage of *Listeria*-related recalls dropped and *Salmonella*-related recalls rose. (See Table 1.)

Other reasons for recall include mislabeling not involving allergens; use of excess or unapproved chemical, color, or drug; norovirus risk; processing or pasteurization issues; pathogenic *E.coli*; unspecified mold or bacteria; botulism; not inspected by USDA; lack of Hazard Analysis and Critical Control Points plan; pest infestation; Specified Risk Material; *Bacillus cereus*; histamine; scromboid toxin; and *giardia*.

Facilities certified in one of the GFSI benchmarked audit schemes were associated with 192 recalls, or 25.8 percent of the total. This is slightly higher than the prior period, May 1, 2011 to April 30, 2012, (24.8 percent). There were 90 recalls where the notice and/or enforcement report specifically listed a non-U.S. facility as the site where the recalled goods were produced. In all, 19 of the 90 non-U.S. facilities (21 percent) were GFSI-certified.

Of the 216 recalls related allergens/sulfites, 29 percent were associated with GFSI-certified facilities. When all pathogens reported are combined, there were 290 food recalls (39 percent) associated with the presence of specific pathogens; of that number, 85 pathogen-related recalls (29 percent) were associated with GFSI-certified facilities in the U.S.

SQF was the most frequently held GFSI certification scheme among U.S. suppliers. The SQF supplier database contained over 3,400 certified sites in the U.S. at the time of review. The BRC database listed over 1,400 U.S. sites for its food standard, and approximately 55 sites for its packaging standard. The FSSC database listed around 425 certified sites for the "United States," and another 250 sites for the "U.S.A."—geographic distinctions between the two were not clear. IFS reported approximately 50 sites in the U.S. for its food standard and 60 sites for its logistics standard. We were unable to determine the number of certified sites for GlobalGAP or PrimusGFS. The PrimusGFS database lists sites by crop; one site may have more than one certified crop and more than one entry in the database. The GlobalGAP database maintains the previously-referenced privacy option.

The proportion of certified sites involved in recalls was relatively constant among the GFSI-certification schemes, and mostly unchanged from the prior review period. Approximately 2 percent to 3 percent of each scheme's certified sites in the U.S. issued recalls, in those schemes where approximate count of certified sites was available. (See Table 2.) It would not be advisable to contrast one certification scheme against another in this respect; there is sizeable variability in a product's risk among facilities certified in one scheme or another. More recalls might be anticipated from high-risk raw agricultural commodities, compared to low-risk foods and/or processing plants with firm kill steps. The BRC does not include primary producers such as farming operations. And, although FSSC shows 650 manufacturing sites in the U.S., approximately 85 of those sites are associated with one large business entity processing low-risk beverages. In contrast, most sites certified by PrimusGFS involve farms and packing houses and higher-risk food. So, in the main, it should be less useful to undertake scheme-to-scheme comparisons than to look at GFSI schemes in the aggregate. Meantime, there were six operations issuing recalls that held more than one GFSI certification.

The role of raw material suppliers is underscored in the recall data for this period. No matter how many operational preventive controls a facility puts in place, if an ingredient that came in

Certification	Number of Recalls	Estimated U.S. Certified Facilities	Allergen	Pathogen	Foreign Material	Other
SQF	126	3,400	36	50	22	18
BRC	38	1,400 food, 55 packaging	13	16	3	6
FSSC	22	650	0	4	12	6
PrimusGFS	5	Undetermined	0	1	4	0
GlobalGAP	2	Undetermined	0	2	0	0
IFS	1	50 food, 60 logistics	1	0	0	0

Table 2: Recalls Generated by Operations with GFSI Scheme Certification.

Reason for Recall	Percent of Recalls May 2012 to April 2013	Percent of Recalls May 2011 to April 2012	Percent of Category GFSI Certified May 2012 to April 2013	Percent of Category GFSI Certified May 2011 to April 2012
Allergen	29%	35%	22.8%	27.5%
Salmonella	19%	14%	30.5%	33%
Listeria	14%	19%	31.7%	22%
Foreign Material	9%	6%	42.8%	57%

Table 1: Year-Over-Year Recalls and Percent of Category with GFSI Certification.

the door was already contaminated, the food safety burden greatly intensifies. In this data set, 22 percent of recall notices listed reasons related to raw material suppliers. At least 57 recall notices cited peanuts potentially contaminated with *Salmonella* as the trigger for the recall from peanuts grown at a single operation run by Sunland Inc. The actual number of recalls involving Sunland products could have been higher; there's public visibility only when organizations specifically list a supplier's name in their recall notice, and many do not.

In Sunland's case, the peanut recall led to the company's downfall. In October 2013, citing up to $100 million in liabilities, Sunland filed for Chapter 7 bankruptcy liquidation and closed all operations. The firm recalled all of its products one year earlier. Subsequent administrative actions by FDA resulted in a shutdown; operations didn't resume for seven months and then, could not be sustained.

At least 39 recalls were attributable to FDA's de-listing of Korea on the Interstate Certified Shellfish Shippers List. In June 2012, FDA urged food industry to remove from market all molluscan shellfish from Korea, as the fish and any prepared items with them as ingredients may have been exposed to human fecal waste and potentially norovirus.

At least 26 recall notices involved mangoes grown in Mexico that were associated with outbreaks of *Salmonella Braenderup* and *Salmonella Worthington*, traced to Agricola Daniella in September 2012. An import alert levied by FDA against Agricola mangos wasn't lifted until July 2013. The *Salmonella* outbreaks impacted the entire industry long term as they prompted FDA to declare mangoes a "high-risk" food, promising increased inspections at U.S. ports of entry and a characteristically longer hold time anticipated for mangoes going through the port inspection process.

Discussion

Perhaps the most perplexing part of the recall data is the huge number of allergen-related items, both among GFSI and non-GFSI certified operations. Often allergen recalls are unrelated to complex variables involving microbiology, chemistry, soil conditions, or processing technology. The allergen recalls involve operational mistakes—simple errors with big consequences: Failure to load the correct packaging film; failure to review/approve a label; failure to read a vendor's Certificate of Analysis to notice the allergen content of an ingredient; failure to test for the allergen of interest during production line startup or changeover; or failure to use separate utensils for specific allergens. These are just some of the operational mistakes that have occurred, and on the surface would seem that they are easy to fix. But that apparently is not the case; allergen-related problems have been the top reasons for food recalls in the U.S. for a number of years. Fortunately, a very small number of illnesses have resulted from the allergen errors. However, financial consequences can be weighty.

Costs of recall are substantial for downtime, facility modification, product retrieval and destruction, and FDA or USDA investigation. In the 2011 GMA report, over 81 percent of survey respondents described financial consequences of a recall as either "significant" or "catastrophic," with the highest recall costs stemming from business interruption. Survey participants also consistently listed brand protection as a top concern.

The number of recalls attributable to raw material supplier issues suggests a deeper look at one requirement for all the GFSI-benchmarked schemes—the requirement to qualify and approve suppliers. The GFSI Scheme Scope and Key Elements, Version 6.3, states the following.

Clause FSM 15: "The standard shall require that the organization control purchasing processes to ensure that all externally sourced materials and services, which have an effect on food safety, conform to requirements. Where an organization chooses to outsource any process that may have an effect on food safety, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the food safety system."

Clause FSM 16: "The standard shall require that the organization establish, implement and maintain procedures for the evaluation, approval and continued monitoring of suppliers, which have an effect on food safety. The results of evaluations, investigations and follow up actions shall be recorded."

Because GFSI is a document that outlines elements of a food safety management system for benchmarking standards, it does not have details about how facilities should comply with the requirement. The various GFSI schemes state specific measures and verifications to include in supplier approval programs, and in some cases, specific guidelines for auditors on how to evaluate these programs.

Meantime, in proposed regulation under the Food Safety Modernization Act (FSMA), a supplier approval program is not specifically mandated for domestic operations. However, FDA cites the GFSI framework and SQF as tools for supplier verification. Citing the costs associated with these programs, FDA had solicited comment on whether requiring supplier verification be part of a final rule. For foreign suppliers, the situation is different. Under proposed FSMA rules, exporters into the U.S. must assure that a manufacturer/supplier of raw material is in compliance with FSMA Section103, Preventive Controls; FSMA Section 105, Produce Safety; and FSMA Section 303, Certification of High Risk Foods (when adopted). Importer requirements include not only verifying its exporter's compliance, but also the exporter's suppliers' compliance. This suggests retailers may assume new responsibility and potential liability when they're considered to be the "importer."

It is difficult to evaluate with certainty and precision just how the GFSI has impacted the number or extent of food recalls. Public data sources offer limited visibility to relevant detail, and a true comparison would be done on a company-by-company basis with evaluation for pre- and post-GFSI certification periods. If GFSI prevalence increases, and the rigor and consistency of certification audits are sustained, a decreasing trend is expected, i.e., more GFSI certifications and fewer recalls among operations which adopt GFSI-benchmarked schemes. And, impacts resulting from FSMA also remain to be seen once those regulations solidify. ■

Dr. Moyers is a consultant and trainer in food quality and safety with more than 20 years experience in industry and academia. She provides training, consulting, and troubleshooting services to facilities large and small. Reach her at moyers@floridafood.org.

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The Paperless Microbiology Laboratory

Linking LIMS with an automated approach is allowing one lab to improve the progress of its sample workflow

BY **NICOLA WILSON, PHD,** AND **JOHN BOOTHER**

Westward Laboratories is a microbiology laboratory based in the U.K. that conducts daily routine microbiological testing on finished products, regular pathogen tests for evidence of *Salmonella*, *Listeria*, *E. coli*, and other food poisoning organisms, as well as environmental monitoring. Each month the lab handles over 44,000 tests, almost all are microbiological analyses, such as total viable count, yeast and mold, coliforms, *Enterobacteriaceae*, etc. Around 200,000 samples are processed each year, with almost half a million tests performed. The lab complies with the current United Kingdom Accreditation Service (UKAS) requirements and helps to ensure food manufacturers are implementing Hazard Analysis and Critical Control Points (HACCP). By adopting a Laboratory Information Management System (LIMS) as its backbone and using automated microbiology equipment, Westward Laboratories has developed almost production line techniques to handle the sample throughput. With the LIMS managing the results and report formats for different customers, and the utilization of a specially developed web reporting system, reports and invoices can be accessed online or sent electronically to customers to minimize the use of paper.

Background

Westward Laboratories was established in 1992 following the Food Safety Act of 1990 which required food manufacturers to monitor their processes, practices, and finished products. Although part of the Samworth Brothers group, Westward Labs is an independent food testing facility and has to compete for business from other group members and from external companies. Westward Labs holds the ISO17025 standard and is accredited by UKAS and leading supermarket outlets such as Marks & Spencer and Tesco. Over the years, increasing sample throughput has led to the need for innovation and the use of automation and mechanization technology to keep up with demand.

Lab Workflow

All received samples are registered, tests are assigned, labels are produced for each test suite, and then the samples are placed in a large fridge prior to entering the lab. Samples are then collected by lab staff and prepared prior to being plated. Samples are weighed out and then placed in a holding fridge prior to dilution and plating. Workflow in the lab is very conventional with samples moving through from registration to being put in the incubator as quickly as possible. After incubation, samples are counted, the results recorded, reports prepared and issued, and invoices prepared. Most of the samples received are processed during the same day.

Automating the Process

One of the key factors in the laboratory workflow process is the need to track and trace the samples and associated results to fully comply with the regulatory requirements. To help, Westward Laboratories uses the Matrix LIMS from Autoscribe Ltd., which can be readily tailored to the needs of individual laboratories and provide comprehensive audit trails, version control, and sample tracking functionality. The "OneTime configuration tools" within Matrix allow the system to be configured without the use of custom programming or esoteric basic scripting tools. A configuration wizard allows free choice of screens, workflows and menu designs, customer specific tables/modules, multiple screens for the same function (e.g. registration screens optimized for each sample category), and multiple sample numbering systems. These tools also allow the system to be further configured or reconfigured to keep it in step with any changes to the laboratory workflow or business practices. All samples are booked into the Matrix LIMS on arrival at the laboratory, and once registered, barcode labels are generated, one for each test group that they will undergo. The labels are configurable and could include a barcode, a unique human readable sample code, sample weight, sample description, and a list of the tests required. Registration screens have been created for individual sample types. For example, the registration screen for swabs differs from the general sample registration screen.

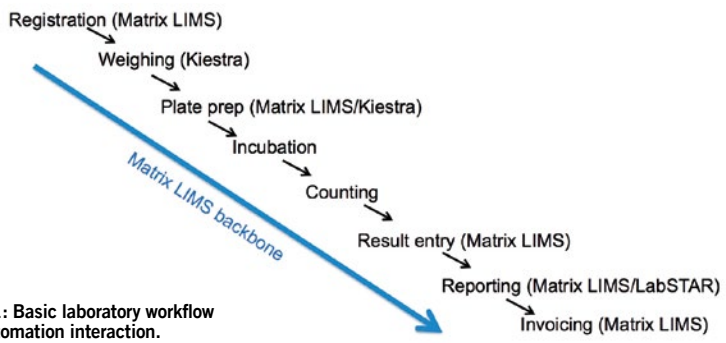

Figure 1: Basic laboratory workflow with automation interaction.

WESTWARD LABORATORIES

Further automation is provided by systems from Kiestra Lab Automation, which control weighing and dilution operations, automated plate preparation, and are used to prepare the media used in the plates. These systems are linked to the LIMS to determine which tests are required. Dilution is performed by Kiestra's gravimetric dilutor, the SynergA, which is connected to a PC via TraceA software that provides full traceability of all dilution operations. In fully automatic mode, the sample barcode includes information about the type of dilution required (sample information including the weight of sample and dilution factor is also recorded giving improved traceability). When the sample barcode is scanned, the system automatically checks to see if the starting weight is within the predefined limits, selects the bottle of media to be used (if several are connected at the same time), makes the dilution, and checks if the accuracy is correct. The TraceA software package ensures all relevant data is stored automatically (date, time, analyst ID, sample ID, weight of sample, media batch number, weight added, and media).

Every sample tested requires a petri dish (apart from pathogen samples that are tested in a separate laboratory). Dishes are automatically labeled with a barcode at a rate of 1,000 per hour using Kiestra's BarcodA system, which can also code tubes and bottles. Real-time barcoding dramatically reduces the transcription error rates to only 1 in 36 trillion characters, compared to manual coding/reading/writing where there can be at least 1 error in 300 characters. This barcode contains all of the important sample information such as use-by date. With this barcode, every sample is uniquely recorded, resulting in full sample traceability for the laboratory. Sample barcodes are scanned at the pipetting bench and the LIMS then sends the tests associated with the particular sample so that the petri dishes can be labeled with a second barcode specific for each test. The technician instantly receives the right set of test plates per sample. After pipetting, a Kiestra AgarrA module automatically scans the barcode on each dish and pours the plate with the correct molten media for the test—after which mixing, solidifying, and stacking takes place. The laboratory estimates that there has been a 30 percent saving on media costs since this system was installed due to more accurate dispensing of media. Following incubation the plates are counted—by hand. Westward Laboratories opted not to use automated plate counters due to the possible presence of food particles on the plates leading to false positives. Results are entered into the LIMS and are checked before they are made available for reporting. The LIMS also holds information about test costs, etc. so it is used to produce invoices for the customers. The entire system has been developed around a Matrix LIMS backbone with other tools being used at appropriate stages in the lab workflow to provide added speed and functionality to the system. Figure 1 shows this interaction in the workflow.

> Reports and invoices can be accessed online or sent electronically to customers to minimize the use of paper.

Paperless Reporting

Matrix LIMS enables authorized users in the lab to modify existing reports or to create new ones. This is used extensively to ensure customers receive whatever reports/data analysis and interpretation they require such as daily, weekly, and monthly retailer reports. Whilst the LIMS system allows paper in the laboratory itself to be kept to a minimum, Westward Laboratories also recognized the opportunity to develop a paperless reporting system for its customers, so its in-house IT developed LabSTAR (Lab Service for Trend Analysis and Results). It's a web-based reporting module which replaced an earlier system based on Excel. It queries the LIMS database but is separate from the LIMS itself. This approach was chosen because the customers did not require access to the LIMS itself, only to the reporting module which does the database querying. LabSTAR is used for results, trends, and exception reporting. It features a simple website with user name and password login and allows access to sample registration and results on a *read only* basis.

In a further move towards paperless reporting, the LIMS holds all the pricing information for tests enabling invoices to be produced for online access or as downloadable PDFs. The LabSTAR/Matrix LIMS combination also provides other paperless functionality for customers. All of the Manuals, Standard Operating Procedures, Specifications, even price lists are held in a database and can be accessed through the LabSTAR interface.

Additional Benefits

Whilst the system established at Westward labs has significant benefits for customers and the busy analysis team alike, there are also additional benefits to the operation of the lab. Preparation of the media used for incubation is currently managed by the Kiestra system. The SolventA software contains the media recipes and also controls batch numbers and expiry dates for media stock. Another piece of software, RegistrA, records autoclave cycles, etc. The media usage is managed by Matrix LIMs and there is a screen that prominently displays the amount of media used and the stock level. The levels are calculated from the data about the number and types of required tests and the amount of plates already prepared. This acts as an early warning system for media shortages, but also ensures that an excessive amount is not made available.

More recently, a temperature monitoring system (IceSpy from IMC Group) was installed for the fridges, water baths, and incubators in the laboratory. It replaced the manual task of going around with a sheet of paper on a clipboard to record the various temperatures. It also, of course, obviates the need to open a fridge door to read the temperature.

This automated and paperless approach adopted by Westward brings other significant benefits, including cost savings—agar, paper, and reporting; reduced human errors; bespoke trend analysis, period reports, and decision support tools; efficient information dissemination; increased productivity and efficiency; and improved tracking and traceability. ■

Dr. Wilson, general manager at Westward Laboratories, has been an industrial microbiologist for 16 years and is a technical expert in laboratory management and food safety. She can be reached at +44 1579 386219. **Boother** is managing director at Autoscribe Ltd. and has had involvement in around 5000 LIMS projects. Reach him at john.boother@autoscribe.co.uk.

Shutting the Door on Pathogens

Specially engineered doorways minimize foods' exposure to airborne pathogens—satisfying compliance standards set forth by HACCP and other safety programs

BY **KURT ANGERMEIER**

The ability of roll-up doors to take a hit and then quickly reset minimizes room exposure to airborne microorganisms.

RYTEC HIGH PERFORMANCE DOORS

Most of our food travels a long way from the farm to the dinner plate. The most crucial yet controllable part of that route is within the four walls of the food processing plant. After raw food hits the delivery dock at the processing facility, it can travel hundreds of feet through various rooms as it is transformed into packaged product. Food can be exposed to any number of contaminants at critical control points.

Pathogen Air Raid

Airborne microorganisms represent a serious threat to quality and safety as product moves from one part of the processing plant to another. According to a study commissioned by the American Society of Heating, Refrigerating, and Air Conditioning Engineers and conducted by Dr. A. J. Heber of Purdue University's Department of Agriculture and Biological Engineering, these bioaerosol emissions may be carried throughout a processing plant via airflow through doorways and other openings. Dealing with these doorways can reduce the flow of contaminated air and mean additional benefits for the food operation as well.

An aerosol is the suspension of fine solid or liquid particles in gas. Bioaerosols are airborne contaminants that include bacteria, fungi, viruses, and pollen. These free-floating microorganisms may be present in the air as solids (dust) or as liquids (condensation and water) and they are an important bacterial vehicle.

In their paper "Controlling Airborne Microbial Contamination," Chris Kerth and Crystal Braden from Auburn University state that "with air being considered a potential source of product contamination, the avenues which can allow the air inside the facility to become contamination must be controlled."

It's said simple practices such as keeping doors closed is essential in controlling air contamination. That's easier said than done. Doors with heavy traffic suffer from maintenance issues that arise from frequent usage and damage caused by crashes. Deficiencies in door design can mean that even when the door is closed, contaminants still find a way through. As a result, proper door selection becomes important in preventing contamination.

Doors—Passage and Protection

Walls and doors are used to separate clean and unclean areas, but improperly sealed doorways can defeat the protection these barriers provide. The door industry has engineered doorway solutions that minimize bioaerosol travel and transport as product moves through the process. These doors not only meet the demand for increased productivity and reduced maintenance costs, but also satisfy compliance standards set forth by Hazardous Analysis and Critical Control Points (HACCP) and other food safety programs.

In order to contribute to bioaerosol flow suppression, doors should offer the following measures of protection.

Leaving Microbials Behind in the Rush. According to Dr. Heber, "the speed at which a door operates definitely could affect dispersion or movement of bioaerosol emissions to clean rooms in a food processing operation."

Slow operating doors compromise quality and safety by enabling dust and fumes to travel with the forklift between areas. Slow speed can also reduce control over desired temperatures, threatening food quality. The faster a door operates, the more effective it serves as a barrier.

Rapid door operation means that food is not only moved faster along the process, but it is moved safer. Seconds count when it comes to outracing bioaerosols while maximizing efficient product handling. For an 8-foot high door that opens at speeds up to 100 inches per second, the doorway will be open for as little as 5 seconds as the forklift hurries through.

High-speed doors and minimal opening time mean doorways are closed as much as possible, maintaining air balance.

Protection All the Way Around. A tight seal on all four sides of the door panel is as crucial as the seal on product packaging. The optimal roll-up door barrier consists of full-height seals enclosed by the side guides and brush or vinyl seals along the header and bottom bar. If seals prevent air infiltration and energy loss, pathogens can be stopped at the door.

This seal is compromised when the door is hit by a forklift. The doorway could be unprotected for hours until the repair crew arrives or for days if there is panel damage. Repairs can disrupt the flow of ingredients and products to the production and shipping areas, especially if there are few doors into the room.

For a high-speed door, the rapid opening should make these occasions rare. But when collisions do happen, the door panel should have the capability to break away from its guide to prevent damage. The ability to quickly reset the door into the guides minimizes room exposure.

In this high-speed setting, high performance puts high demands on the door. Effective counterweight design eliminates stress and overworking of the door motor.

Clean Getaway. The door must be as easily cleaned and sanitized as all other processing equipment and containers used in the process. Like the equipment, the doors must be made of nontoxic materials, particularly if the doorway leads into areas designated as clean rooms.

These kinds of doors must meet the requirements for current Good Manufacturing Practices (cGMP) as defined under the Food, Drug, and Cosmetic Act, which dictates that equipment and utensils in food production areas must be chosen and designed to prevent disease and adulteration. Metal parts should be constructed of stainless steel, including the frame and the roll-up drum. Some models have removable frames for easy cleaning.

For roll-up style doors, nonporous USDA/FDA approved curtain fabric enables doors to easily shed dirt and debris during wash down. Door curtains should be completely extended when doors are closed, preventing microorganisms and debris from collecting around the drums.

Chasing Moisture Away. Major sources of contamination in food processing facilities are wastewater, rinse water, and spilled product that become aerosolized. Airborne bacteria, yeast, and

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mold are generated in processing facilities by heating, ventilation, and air conditioning systems. These systems contribute airborne microorganisms under normal operation because they provide fertile areas for growth due to moisture.

Sink and floor drains can harbor microorganisms because they are humid and contain nutrients from wastewater that provide a fertile growth environment. Flooded drains cause microorganisms on the surface to become aerosolized and air disperses them, causing increased levels of aerosolized bacteria in the food processing facility. High pressure spraying also causes an increased level of aerosolized bacteria.

Here's where the door itself, especially a roll-up door, can sometimes become part of the solution yet part of the problem. The curtain plays an excellent role as a large catcher's mitt for aerosolized microorganisms, blocking the entry of these invaders into the next step in the process. But these pathogens are rolled up with the door curtain as it opens. As product passes underneath the opening door, the bioaerosol can drip on the food below.

A roll-up door can be outfitted with a pneumatic drip-catch tray that moves under the roll drum when the door opens to prevent adulteration and contamination. When the tray is in place, contaminated liquid is stopped from raining on the food.

After traffic passes through the doorway, the tray moves out of the threshold and back to the original position, allowing the door to close. These trays do not interfere with efficient door operation, and they are the first line of defense in enabling compliance with cGMP, HACCP, USDA, and other regulations.

Because of floor drains and water accumulation from wash downs, the floor is a common source for bacteria growth and the roll-door bottom bar can make contact with these contaminant pools. As another measure of protection against this microorganism habitat and bioaerosols, manufacturers are adding a sloped bottom bar to their roll-up curtains. The design prevents water from dripping on product by channeling it off to the side of the doorway.

No Pooling. Walls that separate freezer areas must be properly insulated, as must the doors that cover the doorways leading into them. Doors that fail to minimize heat transfer can provide a cool surface on the warm room side of the door, turning the door panel into a condenser and creating water droplets and an environment for microorganism growth.

Whether the doors are solid panel or, for high-traffic doorways, roll-up style, the doorways must be insulated properly to handle the temperature differentials between the freezer area and the room outside. Even roll-up doors with insulated curtains do not equal the insulation provided by a solid wall. And with heavy traffic, these doors rarely stay closed for long. To minimize air infiltration, these doors must open and close rapidly.

When door are shut, curtains must provide some measure of insulation. When doors fill the role as vapor barriers between cold room and the warmer area on other side of wall, the operation enjoys the dual benefit of minimizing energy loss and reducing contaminated air infiltration.

An uninsulated door on this kind of a doorway becomes a condenser when the cold room chills the warm side of the door. When the door is closed for a period of time between accesses, moist air can hit the chilled panel surface. Water will form and then pool up on the floor. Not only does the pooled water create a pathogen breeding ground, but the slippery floor can lead to worker injuries.

No Admittance for Undesirables

As always in the real world of the plant floor, it is impossible to keep airborne bacteria, yeast, and mold in food processing areas at a zero level. Nevertheless, combating the assault of airborne contamination on food is a multifront war that processors fight with a variety of weapons.

Installation of recirculating air infiltration units, constant monitoring, consistent room temperatures, and even limiting employee traffic are among the many means to reduce contamination throughout the route to the shipping door. Though total confinement of pathogens to their place of origin is beyond practicality, proper door selection and application can ensure that food travels through the plant safely and that an unacceptable level of the microorganisms do not. ■

Angermeier is vice-president, marketing, for Rytec High Performance Doors. Reach him at kangermeier@rytecdoors.com.

Sanitation & HACCP

BY **DAVID MCCARTHY**

Having a wholesale food manufacturer comply with HACCP regulations requires a written HACCP plan with supporting good manufacturing practices and sanitation standard operating procedures.

Sanitation of process equipment is done in two ways. Clean-out-of-place systems are used for smaller scale operations where equipment is dissembled and manually cleaned. They're generally comprised of basins or portable tanks providing rinse and wash solutions to clean the equipment. Larger scale operations utilize clean-in-place systems that circulate, rinse, wash, and sanitize solutions through assembled process equipment. Critical Control Points (CCP) typically include flow rate, temperature, contact time, and chemical solution strength.

In automated systems, governmental compliance was usually verified with electromechanical recorders documenting the CCP values. These recorders are now routinely replaced with secured electronic data storage systems. The systems must be compliant with FDA regulation 21 CFR Part 11, which defines criteria under which electronic records and electronic signatures are deemed trustworthy.

Biosecurity has become an increasing focus over the last several years. This includes traceability requirements for incoming ingredients and outgoing products to help better manage effective responses to natural or man-made food safety events.

New technologies include "green" approaches to sanitation such as Electrochemical Activation, which use significantly less water, chemicals, utilities, and time with no toxic byproducts. The plummeting cost of data storage compared to even a few years ago allows for "moment-to-moment" recording of all sensor and device states in the processing system. Associated analytics provide deep insight into the behavior of such systems yielding ever increasing efficiency and security of operations.

McCarthy is president and chief executive officer of TriCore, Inc., a systems integration firm headquartered in Racine, Wis. Reach him at info@tricore.com.

NEW PRODUCTS

Yeast and Mold Indicator Test

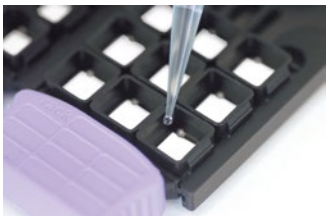
The Petrifilm Rapid Yeast and Mold Count Plate is an indicator test that enables the detection of yeasts and molds in as little as 48 hours, opposed to the typical five to seven day incubation period. The plate improves time-to-result, productivity gains, finished goods inventory, and product shelf life by using a three-step process: Inoculation, Incubation, and Enumeration. It also prevents colonies from spreading or overlapping and it performs on both low and high water activity foods, and can be used for air, swab, or surface contact environmental testing. **3M Food Safety, 888-364-3577, www.3M.com/foodsafety.**

Ozone Analyzer

The UV1 is specifically designed for integration with ozone treatment systems in the food industry. It controls the ozone treatment system to produce the right amount of ozone for application. Analyzer can also monitor around human health and safety limits, shutting off the generator or triggering an alarm when acceptable limits are breached. **Aeroqual, www.aeroqual.com.**

Screening for Coccidiostats

Randox Food Diagnostics has released its multi-analyte screening test for coccidiostats in the poultry market. Coccidiosis is a parasitic disease of animal intestinal tracts caused by coccidian protozoa. To prevent infection, farmers can administer prophylactic antiprotozoal coccidiostats in feed, which



increases the chance that coccidiostat residues are retained in both poultry and eggs. As a result, the company's Biochip Array Technology can detect and quantifyy the whole range of commonly-used coccidiostats. It's optimized for multiplex testing, identifying up to 22 different analyte from a single sample. **Randox Food Diagnostics, www.randoxfooddiagnostics.com.**

Automatic Saccharimeter

The SAC-i Automatic Polarimeter provides high accuracy measurement over a wide range and improved usability with its touchscreen. Measurement stability in 13 seconds (4 seconds in consecutive measurement modes). Compliant with ICUMSA and 21 CFR Part 11 standards, it communicates with the RX series Digital Automatic Refractometer for automatic purity measurement. The flow cell attachment allows users to measure one sample after another by simply pouring a new batch in to replace the previous one. **Paul N. Gardner Co., 954-946-9454, www.gardco.com.**

Ready-to-Use QC Microorganisms

Microbiologics has extended its offering of Shiga toxin-producing *E. coli* (STEC) products to now include Epower, a QC microorganism product that delivers a specific number of colony forming units and is used for quantitative microbiological quality control testing. The microorganisms are packaged in a vial of 10 lyophilized pellets consisting of a single enumerated microorganism strain. Also included is a peel-off Certificate of Assay detailing the identity and mean assay value of the pellets for documentation. In addition, the pellets can be manipulated to deliver a wide range of CFU concentrations, or multiple strains can be combined for a mixed microorganism population. **Microbiologics, 320-253-7400, www.microbiologics.com.**

Compact Spectrometer

The FOURIER 60 is a permanent-magnet based, benchtop FT-NMR spectrometer that has an option for automatic sample changes, a built-in pressurized air supply, and an option for variable sample temperature control. It uses cryogen-free, permanent magnet technology, resulting in a small footprint and low weight for sitting on standard lab benches. The FOURIER 60 is also compatible with TopSpin operating and integrated analysis software, as well as the industry-standard 5 mm NMR sample tube format. **Bruker, www.bruker.com.**

In Other Product News

BioControl Systems receives AOAC-PTM certification for its Assurance GDS *Salmonella* Tq mEHEC method.

Union Jack now offers a full line of professional cleaning brushes and tools from U.K.-based **Hill Brush.**

DuPont Nutrition & Health's BAX System receives AOAC-PTM certification for detecting Shiga toxin-producing *E.coli* (STEC).

The Modernization of Diagnostic Testing

Today's diagnostic test kits are created to be in-tune to the ever-changing needs of the market

By **Caitlin Cromley**

THE DEMAND FOR RAPID AND RELIABLE pathogen testing in the food industry has steadily increased, and the latest diagnostic tests are willing to rise up to the challenge. The rules have drastically changed with the implementation of the Food Safety Modernization Act (FSMA). Among some of the major alterations is the shift from Hazard Analysis and Critical Control Points to Hazard Analysis and Risk-based Preventive Controls, which aims to make sure the U.S. food supply is safe by changing the focus from response to contamination, to prevention itself.

Companies must adapt to the modernized regulations, and it could prove to be a difficult task. Wendy Lauer, senior product manager of Bio-Rad's Food Science Division, states, "The whole process is very new and requires a great deal of effort. We're seeing more of an emphasis on traceability and verification."

Benjamin Pascal, co-founder and chief business officer at Invisible Sentinel, Inc., adds that creating diagnostics for the food market can be difficult due to the challenge of making tests compatible across a wide variety of matrices. However, the end goal reflects the shifting priorities. Pascal says, "While speed is important, ease of use and reduced costs are our top priority, and there is now a greater push to build rapid tests for other targets including spoilage organisms."

In addition, firms are responding to FSMA by developing new solutions to suit the market's latest demands. Lauer says Bio-Rad has come out with iQ-Check Prep automation system, "a robot that provides traceability, flags errors, and prevents cross-contamination."

Invisible Sentinel's novel technology, Veriflow, keeps the focus on cost-effective molecular testing. And there's plans to announce a custom diagnostic test for a spoilage organism in December.

The future of diagnostic testing is one of uncertainty due to the numerous directions it could take. However, Lauer presumes, "It will be more of the same, with continued emphasis on accuracy, traceability, and verification. Specific results will need to be documented."

Pascal is confident that pathogen testing volume will continue to increase, "with an emphasis on accessible molecular diagnostics, which can be quickly targeted to pathogens but also to quality indicator organisms."■

Cromley is an editorial intern for Wiley.

Bio-Rad Laboratories, Inc.
Wendy Lauer
2000 Alfred Nobel Drive
Hercules, CA 94547

Bio-Rad PCR Solution: Your Solution for Rapid and Accurate Results

The Bio-Rad PCR solution brings real-time PCR pathogen detection to low, medium and high throughput labs. The iQ-Check Prep combines the power of automation with a full range of real-time PCR test kits designed to reduce the time and cost associated with food pathogen detection without disrupting an existing workflow.

http://www.foodscience.bio-rad.com

Veriflow™ – Innovative Molecular Detection made Simple, Accessible and Affordable

Veriflow™ represents the FIRST AOAC-RI certified Molecular Flow-based Assay. The patented vertical flow technology allows for the sensitivity of PCR, but with the ease-of-use of a handheld flow-based test. Veriflow™ delivers reliable results within 18-24 hours streamlining workflow and providing cost-savings. Test Kits include:

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- *Veriflow™ Listeria monocytogenes*
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- *Veriflow™ Salmonella*

www.invisiblesentinel.com/technology/

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Randox Food Diagnostics provide reliable, cost effective food safety screening solutions.

Randox Food Diagnostics offer food safety screening solutions using the multi-analyte, semi-quantitative drug residue analyser; the Evidence Investigator. This multiplex platform detects antimicrobials, growth promoters and drugs of abuse in animals and foodstuffs. The Evidence Investigator provides simultaneous detection of an extensive list of compounds within various sample matrices.

enquiries@randoxfooddiagnostics.com

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Events

JANUARY

6-8
Food Innovation Conference
Manila
Visit www.novelapproachsystems.com.

22
Methods of Measuring Fruit and Vegetable Quality: Color, Flavor, Texture Workshop
Davis, Calif.
Visit http://postharvest.ucdavis.edu/Education or email pastockdale@ucdavis.edu.

28-30
International Production & Processing Expo
Atlanta, Ga.
Visit ippexpo.com.

FEBRUARY

26-28
Global Food Safety Conference
Anaheim, Calif.
Visit www.tcgffoodsafety.com.

MARCH

2-6
Pittcon Conference & Expo
Chicago, Ill.
Visit www.pittcon.org.

24-27
4-Day Low Acid Foods Workshop Chapman University
Orange, Calif.
Visit www.chapman.edu/bpcs or call 714-997-6566.

APRIL

8-10
Food Safety Summit Expo & Conference
Baltimore, Md.
Visit www.foodsafetysummit.com.

MAY

17-20
asm2014
Boston, Mass.
Visit http://gm.asm.org.

JUNE

3-5
Food Microbiology Short Course
University Park, Penn.
Visit www.agsci.psu.edu/foodmicro or call 877-778-2937.

10-13
United Fresh
Chicago, Ill.
Visit www.unitedfreshshow.org or call 202-303-3400.

18-20
48th Annual Microwave Power Symposium - IMPI 48
New Orleans, La.
Visit www.impi.org or call 804-559-6667.

Innovators

IN FOOD QUALITY & SAFETY

William Frear Made a Case for Food Purity Laws

BY **LORI VALIGRA**

Commercial foods were fraught with impurities in the latter half of the 19th century when they were supplanting home-prepared foodstuffs. These foods arose from a need to feed the growing populations in cities and support an industrializing nation. But the commercial foods were largely unregulated, opening the door for adulteration by adding chemicals to enhance flavor and even covering up and reusing food that had gone bad. This concerned Pennsylvania State University Professor William Frear, PhD, (1855-1921), who took up the charge to analyze potentially tainted food in an effort to protect the quality and purity of the commonwealth's, and the nation's, commercial food supply. This was much needed as he found canned peas laced with copper dioxide to make them look greener, licorice candy blackened using soot, and candy sweetened using lead.

Professor William Frear in his office at Penn State University.

In 1900, he analyzed 11 samples of ketchup or mustard, and found that four contained salicylic acid, which prevented fermentation but also impeded digestion, according to Penn State historian Michael Bezilla. He also found water added—an illegal practice as well—to two of eight lard samples and 21 of 96 milk samples, the latter of which also were found to contain boric acid or formaldehyde preservatives. Dr. Frear, a chemist with a doctorate from Illinois Wesleyan, became known for his testing work, and often appeared as an expert witness for the Commonwealth of Pennsylvania in court cases against alleged food adulterators. In 1900, Pennsylvania had nearly 1,000 cases of alleged adulterations pending in the courts, Bezilla wrote. The commonwealth is now known for having stringent consumer food protection standards, a status largely credited to the work of Dr. Frear.

While having healthy food was a public health issue, political and corporate leaders, as well as the courts, tended to favor the manufacturers at the time. The notion was that government shouldn't interfere in business. Also, state laws did not cover interstate commerce of the food products. Pennsylvania was not alone in having its hands tied as the situation occurred in other states as well.

But popular pressure for more protective food laws was strong, and states began setting up regulatory agencies. There also was public pressure for the federal government to enact uniform and stringent pure food and drug laws. Dr. Frear took a central role in working with some of the agencies and the federal government to try to reverse the problems. He helped organize the first National Pure Food and Drug Congress in Washington, D.C., in 1898. It was attended by agricultural scientists, politicians, social reformers, and some food industry representatives, and was followed by two more congresses.

He also acted as chairman of the food congress' executive committee and headed the Food Standards Committee of the Association of Official Agricultural Chemists. This brought him to work closely with his former boss when he was a chemist at the USDA, food safety pioneer Harvey W. Wiley, MD. While Dr. Wiley is widely credited as having largely written the federal Pure Food and Drug Act of 1906, Dr. Frear headed the committee that devised the guidelines for the Act, which formed the foundation for today's U.S. FDA.

Dr. Frear participated in Dr. Wiley's campaign to get safe food laws passed. Dr. Wiley had brought notoriety to the effort by organizing volunteers, who were known as the "poison squad," to eat meals laced with the harmful chemicals then used as food additives so they could see which ones made them sick. The goal of the so-called "table trial" was to study the human effects of common preservatives in items like ketchup and other condiments, in which they often were used to cover up unsanitary production practices. The volunteers ate meals together, taking in increased doses of preservatives such as borax, benzoate, formaldehyde, sulfites and salicylates. The results were debated, but many people began afterward to avoid foods that contained formaldehyde and other preservatives. And the cause for safe foods got even more publicity.

In 1902, Dr. Frear chaired the FDA's first advisory panel comprising state agriculture officials and scientists who met for days to talk about regulating food nationally. That same year he had pushed for changes to Pennsylvania's food purity laws to require accurate food labeling, which the commonwealth adopted.

During the first case brought by the Pure Food Commission in 1907, Dr. Frear testified that a can of peaches contained sulfurous acid, which was "a poison injurious to health." He also was behind liming studies at the Jordan Soil Fertility Plots and was the chief chemist for Pennsylvania's Dairy and Food Commissioner when he suspected illegal food additives.

Dr. Frear's work is still looked upon as instrumental to Pennsylvania's food labeling laws going into practice. Penn State's biology building on the main campus bears his name. ■

Valigra is a writer based in Harrison, Maine. Reach her at lvaligra@gmail.com.

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