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Intercepting Food Fraud Before It Hits the Shelves

Techniques to identify the authenticity and purity of products are in demand as more counterfeit foods enter the consumer supply chain

BY STEPHEN HARRISON

COVER: © FOTOLIA.COM

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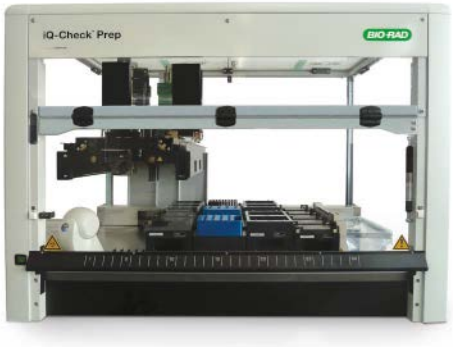

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From The Editor

Being the proud daughter of parents who both were raised on farms in Eastern Europe, I was pleased to learn early in the year that the United Nations declared 2014 as the International Year of Family Farming (IYFF) to highlight the importance of family and smallholder farmers. Throughout the year, organizations like Food Tank joined with Food and Agriculture Organization (FAO) and over 360 civil society and farmers' groups in celebrating the role these farmers play.

According to the FAO, of the more than 570 million farms in the world, more than 500 million are family farms. With the world population expected to reach nine billion by 2050, FAO stresses that family farms can play a key role in scaling up food production to meet the needs of a growing world population. In fact, FAO dedicated its annual report to agricultural innovations in family farming.

The Institute of Food Technologists also put the spotlight on agricultural innovations with its FutureFood 2050 program, which highlights the people and stories leading the efforts in finding solutions to safely feed these nine billion people. The program includes interviews with agriculture pioneers who are mixing and matching technology, both old and new, to boost agricultural production sustainably in the years ahead.

However, in order to accommodate the needs of a growing population, government also needs to support more new and young farmers entering the field of agriculture.

Noting that the global average age of farmers is 55, the Food Tank created a petition calling on government officials to provide more resources, aid, and infrastructure to make farming economically viable and environmentally sustainable for a new generation of farmers and food system leaders.

"Increased access to education means that young people can be a force for innovation on family farms, increasing incomes and well-being for not only farmers, but also local communities," says Mark Holderness, executive secretary, Global Forum on Agricultural Research. "Young people can develop the agricultural sector by applying new technologies to current work methods."

Both in developing and developed countries, family farming is the predominant form of agriculture in the food production sector. The IYFF emphasized that we must do more to support these farmers, especially young farmers. As the Food Tank points out, the future of farming depends on younger generations—people who see agriculture as an opportunity and something they want to do rather than something they feel forced to do.

Marian Zboraj
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FARM TO FORK SAFETY

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NEWS & NOTES

Learning Module for Seafood Product Labeling

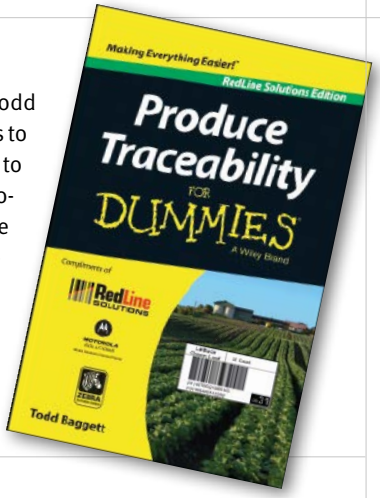
The FDA's online learning module is designed to better assist the seafood industry, retailers, and state regulators in properly labeling seafood products in the U.S. marketplace. Offered on the FDA's website, the module includes a summary of specific laws, regulations, guidance documents, and other materials pertinent to labeling seafood. It also offers tips for identifying mislabeled seafood in the wholesale distribution chain or the point of retail and describes FDA's role in the labeling process.

Analyzing Microbiology Testing

Strategic Consulting recently published its "Industrial Microbiology Market Review, Fourth Edition: Global Review of Microbiology Testing in the Industrial Market." The report tracks and compares past, current, and future microbiology test volumes, market values, and test methods for six sectors of the industrial market, including Food and Beverage. According to the report, more than 90,000 industrial plants worldwide conduct close to 2 billion tests each year, representing a market value of $6.5 billion. Report also includes profiles of major diagnostic companies.

Produce Traceability For Dummies

The new guide, *Produce Traceability For Dummies* by Todd Baggett from RedLine Solutions, helps grower-shippers to understand produce traceability requirements and how to implement them in their own companies. The book provides insight into several topics surrounding produce traceability including the Produce Traceability Initiative, government regulations, choosing a traceability solution, and what to do in the event of a recall. It also shows how implementing the proper traceability solution has the potential to save a company time and money.



FDA to Reach Final Rule on Food Additives

The FDA is expected to reach a final rule by August 2016 regarding its food additive approval process. The FDA has been operating under a proposed rule that allows food manufacturers to get approval of food additives by informing the FDA that the additive is generally recognized as safe. The timeline to reach a final rule was part of a settlement agreement that was reached after the Center for Food Safety sued the FDA, arguing that the proposed rule did not adequately protect consumers from potentially harmful food additives.

The Modernization of U.S. Meat Inspection System

"Meat and Poultry Inspection 2.0," a new report by The Pew Charitable Trusts and the Center for Science in the Public Interest that compares U.S. meat and poultry inspection

practices with those of five other countries, finds that the U.S. is in need of an update to its inspection system to help better protect consumers. One of the recommendations includes having the U.S. require slaughter facilities to collect better information on the status of animals and flocks and regularly monitor data on plant performance.

Business Briefs

AIB introduces a new Environmental Monitoring Consulting Service to assist clients in establishing and improving their programs to comply with FSMA.

Global Food Protection Institute and **International Food Protection Training Institute (IFTPI)** have consolidated and are now operating under the IFTPI brand.

BioSafe Systems opens a new branch in Sparks, Nev. to house its line of activated peroxygen products.

SGS inaugurates a new Pesticides Maximum Residue Limits Laboratory in Mombasa, Kenya.

Eurofins Scientific announces the potential acquisition of **SF Analytical Laboratories**; at press time, the transaction was scheduled to close at the end of November.

Mérieux NutriSciences acquires **Kalite Sistem Laboratories Group,** an independent food testing lab in Turkey.

Washington Report

Whole Genome Sequencing: A Two-Edged, Cutting-Edge Tool

This emerging technology has potential to revolutionize food tracking, but some worry that using it as a monitoring and enforcement tool will expose companies to unnecessary risk

BY **TED AGRES**

Whole genome sequencing (WGS) or next-generation sequencing is an emerging technology that allows scientists to map the genetic sequence of pathogens and other organisms with such precision that they can distinguish between different strains of a bacterium and even slight variations by geography within the same strain. As the cost of gene sequencing equipment continues to decline, FDA and state public health laboratories will increasingly use WGS to investigate outbreaks of foodborne illnesses. They will store the sequenced genomic information in large databases, which will be publicly accessible nationally and internationally.

But FDA will employ WGS not only during outbreaks; the agency announced it will also use WGS to analyze samples from food companies taken during routine inspections in order to monitor compliance with the Food Safety Modernization Act (FSMA) and other regulations. Thus, WGS may become a two-edged sword—one that can quickly pinpoint the source of an outbreak, preventing illness and potentially saving lives, but also a dagger pointed at the hearts of food companies when no outbreak has occurred.

For years, pathogen testing and bacterial subtyping has been performed using pulsed-field gel electrophoresis (PFGE), an older and less sensitive technology. Among other limitations, PFGE cannot differentiate certain strains of *Salmonella* or distinguish between samples of isolates associated with previous contaminations. WGS, on the other hand, is far more reliable and sensitive. By pairing a pathogen's genomic information with geographic information systems, a mapping technology, and applying the principles of evolutionary biology, investigators can identify the root source of contamination—a powerful tool given the rise of food products containing ingredients imported from different countries.

"What genome sequencing allows us to do with food traceback is unprecedented," says Eric Brown, PhD, director of FDA's Division of Microbiology. "It's like upgrading from an old backyard telescope to the Hubble." PFGE has begun to show its age, adds Brian Sauders, PhD, a senior food bacteriologist at the New York State Department of Agriculture & Markets. "PFGE is like looking at a globe of the Earth with only seven labeled continents, while WGS provides better than Google Earth map resolution of the entire world surface complete with names of many key and detailed features and a searchable database with zoom-to-point of reference capabilities," Dr. Sauders wrote in an Association of Public Health Laboratories blog post.

Solving Outbreaks

The U.S. FDA and the CDC used WGS to help solve two widely publicized multistate outbreaks in 2014. The first involved an outbreak of *Listeria monocytogenes*. Reports of listeriosis had been reported as early as August 2013. Investigators first used PFGE to identify cases that may have been part of the outbreak using data archived in PulseNet, a network run by the CDC that connects public health and food regulatory agency laboratories performing molecular surveillance of foodborne infections. After the *Listeria* strain had been isolated from patients, investigators used WGS to definitively link it to Hispanic-style cheese produced by Roos Foods of Kenton, Del. In early 2014, Roos issued a recall and FDA suspended its facility registration.

"This was the first time we used whole genome sequencing to match the environmental and food samples with the CDC's human biological samples and it helped support the agency in taking regulatory

action," says Dr. Brown. "We were able to suspend food production at a facility to minimize an outbreak."

FDA also used WGS to identify a multi-state outbreak strain of *Salmonella Braenderup* and link it to almond and peanut butter manufactured by nSpired Natural Foods Inc. in Ashland, Wash. Recalled brands included Arrowhead Mills, MaraNatha, Trader Joe's, Whole Foods, Safeway, and Kroger. In both cases, FDA inspectors had collected pathogen samples during routine inspections of production facilities; in the case of Roos Foods, they also had collected samples from finished food products.

Going forward, FDA promises to be proactive. "This [genomic] information can be used to help enforce compliance with FDA's food safety rules and remove contaminated food from the food supply before it results in any illness. This is made possible by collecting samples and cataloging gene sequences from food production facilities," the FDA announced in a recent Consumer Update.

While few could object to employing WGS during a foodborne illness outbreak, some worry that using it as a monitoring and enforcement tool will open companies to unnecessary risk. "Regulators want food companies to put in preventive controls, look for problems before they occur, and if they find a problem, to fix it," says David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods. The agency's recent revision proposal of the preventive controls rule for human foods, for example, requires companies to undertake environmental monitoring and product testing for certain high-risk and ready-to-eat foods.

"FDA expects a peanut butter plant to look for *Salmonella* and if they find it, deal with it," Dr. Acheson tells *Food Quality & Safety* magazine. "So if a food company is not actively looking for trouble, so to speak, they will get dinged for not looking." The quandary, Dr. Acheson says, could come after the peanut butter plant has found *Salmonella* somewhere in its facility, say in a crack in the floor, and eliminated it. Could FDA obtain the company's records, its genome sequencing catalog if it has one, and even a sample of the bacteria isolate if retained in a company freezer?

The answer, it seems, is yes to all the above.

FSMA has expanded FDA's authority for obtaining records related to a specific food article that it "reasonably believes is adulterated and presents a serious health threat to include records relating to any article of food that FDA reasonably believes is likely to be affected in a similar manner," says FDA spokesman Douglas Karas. FSMA also allows the agency to obtain records related to "any food having a reasonable probability of causing serious illness or death, and any other article of food it reasonably believes is likely to be affected in a similar manner," he says.

"Once either of the above mentioned circumstances is met, the FDA may request all existing records related to the suspect food and any other food that the FDA believes is likely to be affected in a similar manner that are needed to help determine whether the circumstances that gave rise to the records request exist," Karas tells *Food Quality & Safety* magazine. While declining to respond specifically to Dr. Acheson's hypothetical peanut butter company scenario, Karas noted that in the case of the nSpired recall, "the important point to remember is that the samples were indeed taken by FDA staff during an inspection."

So what should food companies do, especially those dealing with products having a higher risk of potential pathogenic contamination? "If indeed the FDA did have access to a company's whole genome sequencing library—even when there is a for-cause inspection—it would raise some serious questions around the wisdom of having such a library," Dr. Acheson says, because the agency can compare those data with environmental samples taken anywhere in the world. Should the agency find a match, the company will likely find itself in trouble.

And should the company keep a sample of the *Salmonella* isolate in its freezer, "there's an untested question of whether or not the FDA can get that isolate," Dr. Acheson adds. "The FDA can get your records, and they can probably go after the isolate, run it through WGS, and see if it links to an outbreak that happened elsewhere. Obviously, don't keep the isolate. If you found the *Salmonella* and got rid of it, it's gone."

Networks of Data

FDA and other public health agencies are assembling national and even worldwide networks to share genomic information derived from PFGE and WGS analyses of food samples taken during outbreaks, from contaminated food products, environmental sources, and clinical isolates from infected patients. These sequences are archived and available in a global public database called GenomeTrakr, which currently contains more than 7,000 *Salmonella*, *Listeria*, and *E. coli* isolates. The network of local, state, and federal labs is adding about 500 more isolates monthly. "This is huge," Dr. Brown says. "As more laboratories contribute to the database, it's going to be an extraordinary new day in the field of public health and microbiology."

As good as WGS may be, FDA and other agencies are seeking even more powerful pathogen detection tools. In October 2014, FDA and CDC announced food safety "challenges" in which they are offering cash prizes to private sector scientists, academics, entrepreneurs, or innovators who submit the best ideas for "applying novel methodologies to foster revolutionary improvements in foodborne pathogen detection." FDA's Food Safety Challenge targets "cutting-edge techniques" to significantly speed the detection of *Salmonella* "with identification to the subtype/serovar level in minimally processed fresh produce." Of special interest are concepts to accelerate or eliminate sample preparation and/or enrichment in the testing process. The contest "is a means to consider approaches (and possible solutions) through others' eyes, with technology that we may not have considered applicable," explains Palmer Orlandi, PhD, senior science adviser at FDA's Office of Foods and Veterinary Medicine.

"Some of the greatest innovations are born from 'outside-the-box' thinking and this is what we hope to achieve. The prize purse [$500,000] doesn't hurt as an added incentive, either," Dr. Orlandi wrote in an FDA blog posting. The submission deadline was Nov. 9, 2014. Up to five finalists will receive $20,000 each and will be eligible to snag the remainder of the $500,000 jackpot when the winner is announced March 5, 2015. ■

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

Industry Insights

When Food Brands Merge, Consumer Safety Must Come First

Mergers and acquisitions can cause a difficult transition period for plant managers as they struggle to integrate two distinct food safety programs | BY **KATIE MOORE**

As consumers scan the shelves at their local grocer, they rarely put much thought into the manufacturing processes that turned raw ingredients into the food and beverage products they enjoy. But behind the scenes, food and beverage manufacturers know that ensuring the consistent quality and safety consumers take for granted is far from easy. It's a huge responsibility, and when food and beverage companies merge, that task becomes even more challenging.

I've been there. Earlier in my career, I was a plant manager at a large global food company when the company's fresh bakery division was acquired by a competitor. We worked hard to continue producing our customers' favorite baked goods while navigating the complexities of merging our operations. Here are a few things I think can help plant managers make it through the difficult merger/acquisition transition without a hitch.

Metrics are Key

One of the first goals when merging operations must be to understand the data you receive from your plant equipment. In today's connected food manufacturing facilities, equipment constantly churns out information. In some instances, it may be related to divider downtimes due to oven temperature, and in others, it may be metal detector readings. Making sense of all that information and seeing the "big picture" through the volume of machine driven data is the real challenge. During a merger, this can be compounded by the differences in how the formerly separate entities tracked data and measured results.

A smart plant manager will work to ensure that everything is standardized. If you're not comparing "apples to apples," then you are not gleaning smart, actionable insights from your plant floor. Standardizing metrics can be quite a daunting task, and the right approach will be different for each company and set of circumstances. One thing to keep in mind when sorting through standardization is it helps to work with technology that is adaptable and connected to whichever Enterprise Resource Planning, or ERP, system you are running. Standardized metrics and connected machines can ensure you are getting the right information to make smart operational decisions.

Have a Plan for Your Standards

In a perfect world, mergers would be simpler because both organizations would be on the same food safety system. But that may not be the case, so you will need to

figure out quickly which standards you plan to adhere to. Are the plans to follow a Global Food Safety Initiative scheme, like SQF or BRC? Are you running different schemes at different facilities? If so, from an administrative and management standpoint, you need to consider whether it makes sense for the facilities to consolidate under one common platform.

Escalation Protocol

No matter where you are as a company, and in particular during a merger or acquisition process, every employee needs to know what to do when things do not go according to plan—no exceptions. Escalation protocols must be addressed as early as possible so there is no confusion over how to proceed in the case of a problem on the plant floor. When customer safety and costly recalls are at stake, it is important to escalate potential problems quickly so remedial action can be taken before it's too late.

This is another area where technology can help. Providing employees on

Standardized metrics and connected machines can ensure you are getting the right information to make smart operational decisions.

the plant floor with better information, quicker, can be extraordinarily helpful in avoiding or mitigating serious problems. For example, GE Intelligent Platforms' Proficy software can help identify a slight anomaly in an oven before it becomes a bigger problem and you have product that was not baked appropriately. That is why it is so important to foster synergy between your people and your technology—together, they can ensure your consumers and your brand are well protected.

Keep Safety Top of Mind

There are many considerations that go into a merger, but the most important is to ensure continued food safety and quality. While mergers can be a challenging time, I speak from first-hand experience when I say a plant manager can get through it without incident and it can be a smooth process. You simply need to ensure you are listening to the machines and the people—getting the best possible information and gleaning actionable intelligence from that data. With a strong focus on safety and quality, and true line-of-sight into your processes, you will be ready to help guide the combined entity toward a successful future full of satisfied customers. ■

Moore, global industry manager for food and beverage at GE Intelligent Platforms, is advanced HACCP certified through AIB International and is qualified in implementing SQF 2000 systems as an SQF practitioner through the Safe Quality Food Institute. Reach her at katie.moore@ge.com.

Around The World

Food Safety Down Under

Australia's food protection system sets high standards for accountability | BY **LINDA L. LEAKE, MS**

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

Ask Australians to share some of their favorite foods and they are quick to mention hamburgers with beetroot, crab sticks, barbequed snags, pavlova, lamingtons, and Vegemite on toast, just to start the list. These unique local lip-smacking goodies and other tasty foods produced on the continent are the fruits of a highly developed food production and food safety system that extends from farm to fork.

The Australian Department of Agriculture (DoA) Food Regulation Policy Section works with industry and other Australian government agencies, particularly the Department of Health and Aging (DoHA) and Food Standards Australia New Zealand (FSANZ), to ensure Australia's food regulations protect public health and safety, according to Scott Crerar, PhD, manager of FSANZ's Strategic Science, International and Surveillance Section. While New Zealand is not part of the continent, many of its food safety initiatives collaborate with those of Australia.

"Australia's food policy framework is determined by the Legislative and Governance Forum on Food Regulation," Dr. Crerar says. "The Forum is made up of minsters from health and agriculture departments representing the states and territories, as well as the Australian and New Zealand governments. And the Forum is involved in developing food regulatory policy and policy guidelines that must be considered when setting food standards for Australia, which reflect these policies."

There are three levels of government in the food regulatory system and each level plays a role in protecting public health and safety through regulating food, including imported food, Dr. Crerar explains.

Through the Legislative and Governance Forum on Food Regulation, the Commonwealth Government works collaboratively with the New Zealand government and state and territory governments to develop food regulation policy.

DoHA sets policy on food in consultation with Australian state and territory, and New Zealand governments. The bi-national FSANZ develops food standards in line with this policy, which are then published in the Australia New Zealand Food Standards Code, that is, in turn, enforced by state and territory governments.

"The collaborative food regulatory system that has been established within Australia has served the country well and ensures a high level of participation, transparency, and consultation, prior to the finalization of new or revised food standards," Dr. Crerar says.

While there is overarching federal legislation across many sectors, the safety of the domestic food supply is controlled by the individual states and territories through state Departments of Health, Departments of Agriculture/Primary Production, and through statutory authorities.

"The state and territory governments develop and administer food legislation, which gives legal force to the requirements of the Food Standards Code," Dr. Crerar explains. "Regulation of food production at the farm level is typically covered by primary production legislation. State or territory food acts usually cover food processing requirements through to retail sale requirements."

International Food Standards

Australia participates in the development of international food standards to ensure its industry and trade interests are considered, and to restrict any barriers that may inhibit market access and trade potential.

The International Food Standards program (IFS) contributes to the maintenance

and development of international market access opportunities for the Australian food and beverage industries. This is achieved by providing scientific and technical advice in the development of Australian positions in government-to-government negotiations on international food standards.

IFS is principally involved in a range of committees and task forces of the Codex Alimentarius Commission (Codex). Working with Codex Australia, the Australian Codex Contact Point, IFS actively encourages the involvement of Australia's food and beverage industries and government agencies in developing Australia's positions for Codex negotiations.

Through the Food Chain Resilience project within the Agricultural Productivity Division, DoA is involved in the development of two initiatives designed to ensure Australia's preparedness for significant national emergencies—the Critical Infrastructure Resilience Strategy and Food Supply Chain Continuity Planning.

FSANZ develops and promulgates the food standards that are published as the Australia New Zealand Food Standards Code (the Code, a collection of individual food standards that cover the use of ingredients, processing aids, food colors, additives, vitamins, minerals, and chemical and microbiological contaminants). "The standards also cover the composition of foods such as dairy, meat, seafood, and beverages; food hygiene requirements; labeling and mandatory warnings or advisory labels; as well as new technologies and novel foods," Dr. Crerar adds.

"FSANZ only develops the standards and has no role in their implementation," he emphasizes. "Other roles undertaken by FSANZ include surveillance, coordination, and monitoring food recalls and food incidents in Australia."

Under the Code, food processors have a responsibility to implement preventative-based food safety systems and for some sectors HACCP-based food safety programs are mandatory. The role of the State and Territory enforcement agencies is to approve and audit these food safety programs.

"This is a significant point of difference from the United States," Dr. Crerar notes. "Australia has implemented food safety programs, and there is less reliance upon inspection or final product testing. It's all more about systems and audit."

Red Meat

With its national cattle herd at 27.5 million head, including 13.6 million beef cows and heifers, Australia has 3 percent of the world cattle inventory and is the world's seventh largest beef producer, according to Meat & Livestock Australia Limited (MLA), an organization that delivers marketing and research and development services for Australia's cattle, sheep, and goat producers.

"Australia produces 4 percent of the world's beef supply, around 2.2 million tonnes of beef and veal in 2012-2013, and is the third largest beef exporter," says Ian Jenson, MLA's manager of market access science and technology. (One Australian tonne equals 2,204.623 pounds.)

"Beef exports to the U.S. are likely to exceed 300,000 tonnes in 2014, worth more than AU$1.5 billion," Jenson notes. (As of Oct. 31, 2014, 1 AU$ equals .88 US$) "The majority of beef exported from Australia to the U.S. is manufacturing beef or trim for grinding."

SAFEMEAT is the food safety partnership between the Australian red meat industry and the government; its primary role is overseeing and promoting sound management systems in industry to ensure safe and hygienic products. "MLA conducts research and develops systems to satisfy the needs identified by SAFEMEAT," Jenson points out.

A key undertaking within SAFEMEAT is the Microbiological Food Safety Research and Development Program, Jenson says.

"Of relevance to the U.S. market, MLA has invested heavily in understanding the behavior of *E. coli* in our production and processing systems," Jenson relates, "demonstrating a low prevalence of this microbe and a low risk of illness when Australian manufacturing beef is consumed in hamburgers in the United States."

Recent MLA-funded research demonstrated the low prevalence of antibiotic resistant *Salmonella* and *E. coli* in Australian beef cattle. "We want to stay ahead of the market on issues like antibiotic resistance," Jenson emphasizes. "The very low prevalence we have found should give confidence to our customers and it tells us that we don't need to make big changes to our production systems to stay this way."

Dairy

The Australian Dairy Food Safety Regulatory Framework has three elements, says Helen Dornom, manager, sustainability including food safety and integrity at Dairy Australia (DA), a national dairy service organization.

"First, under national legislation, it is mandatory for dairy farms and dairy companies to have a documented and imple-

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mented dairy food safety program that is developed, validated, and approved to national and international standards," Dornom relates. "Secondly, individual programs from farm through to retail or export are verified by government authorities. Third, each business is licensed based on compliance and performance against the food safety program."

A significant exporter of dairy products, Australia shipped approximately AU$3 billion in dairy products during 2013-14, according to the Australian Bureau of Statistics. The U.S., while not in the top 10 relative to Australia's dairy export destinations, imported 6,490 tonnes of dairy products in 2013-2014, including 1,891 tonnes of cheese and 1,386 tonnes of lactose.

Companies exporting dairy products must be registered with the DoA and subject to compliance audits. "These audits are conducted by the State Food Authorities on behalf of the DoA," Dornom explains. "Moreover, importing countries regularly come to Australia to audit the Australian dairy food safety system. For Australian dairy establishments to export to the U.S., they must be registered by the U.S. FDA and may be subject to on-site audits by the FDA."

Even in the absence of any current dairy safety issues, the Australian dairy industry's Issues Management Group (IMG) was developed in 2002 as a network of industry and government stakeholders coordinated by DA. The IMG's objective is to provide a comprehensive and industry-wide approach to address issues that may affect the reputation and future viability of the Australian dairy industry.

"We embrace a cooperative and proactive partnership approach to identify any emerging food safety issues that may affect dairy product safety at any time down the road," Dornom says.

Australia has 3% of the world cattle inventory and is the world's seventh largest beef producer.

Produce

For the major horticultural product groups, fruit and nuts, and then vegetables, gross value of Australian production in 2011-12 was AU$4.09 billion and AU$3.338 billion, respectively, according to the Australian Bureau of Statistics. During that same time period, the country exported AU$1.239 billion of fresh and processed fruit, nuts, and vegetables.

Freshcare, the largest Australian on-farm assurance program for fresh produce, provides food safety and quality and environmental certification services to more than 5,000 participating businesses nationwide, according to Clare Hamilton-Bate, executive officer, Freshcare.

"The recently formed Fresh Produce Safety Centre Limited, a not-for-profit company to enhance Australia and New Zealand fresh produce food safety, is currently looking to review the *Freshcare Guidelines for On-Farm Food Safety for Fresh Produce* and maintain it, unpinned by current research, as a reference tool for Freshcare and other food safety programs," Hamilton-Bate says.

"Freshcare has become the industry standard for food safety in the fresh produce sector," says Alex Livingstone, chief executive officer of Growcom, an organization that provides services to the Queensland horticulture industry. "However, one of our major retailers still has their own food safety standard, and others only accept international food safety standards, benchmarked to the Global Food Safety Initiative (GFSI). In addition, the food service industry has a separate system again. Hence, some producers have to comply with three or more food safety standards."

According to Livingstone, a recent project funded by the not-for-profit Horticulture Australia Limited has engaged retailers, food service providers, and system owners (including Freshcare) to try to define a single food safety standard that could potentially cut more than AU$40 million out of auditing costs borne directly by Australia's produce farmers.

"Freshcare is in the process of seeking GFSI benchmarking, whilst at the same this project is an attempt to align, as much as possible, the food safety standards to reduce compliance costs," Livingstone explains. "The project is making some progress, although each participant will still want to have some components that are unique to them."

"We have been very fortunate that we haven't had a major food safety incident in Australia's horticulture industry and I think that is testament to the high quality of all the standards," Livingstone says. ■

It's mandatory for dairy farms in Australia to have documented and implemented food safety programs.

Foodborne Illness Numbers

The Australian Department of Health recently released its "Foodborne Illness in Australia: Annual Incidence circa 2010" report to better understand the epidemiology of specific pathogens and foodborne causes of gastroenteritis. The report found that there was an "... estimated annual 4.1 million cases of foodborne gastroenteritis acquired in Australia, along with 5,140 cases of non-gastrointestinal illness and 35,840 cases of sequelae. Norovirus, pathogenic *E. coli, Campylobacter spp*., and non-typhoidal *Salmonella spp*. were the most common known causes of foodborne gastroenteritis, although approximately 80 percent of illnesses are of unknown pathogens. Approximately 25 percent of the 15.9 million episodes of gastroenteritis that occur in Australia were estimated to be transmitted by contaminated food. This equates to an average of approximately one episode of foodborne gastroenteritis every five years per person..."—*FQ&S*

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For bonus content on food safety in Australia, go to the December/January 2015 issue on www.foodqualityandsafety.com and click on "Food Safety Down Under."

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A systematic allergen risk assessment approach for industry will enable control of cross-contamination risks and provide accurate allergen information to consumers, allowing them to make informed decisions

BY **EVANGELIA KOMITOPOULOU, PHD**

According to recent data, up to 15 million Americans suffer from food allergies—affecting 1 in every 13 children under the age of 18 and bringing the economic cost of children's food allergies alone to an estimated $25 billion per year. Food allergies among children increased approximately 50 percent between 1997 and 2011 while hospital admissions for severe reactions in children in Europe have risen seven-fold over the past decade. In a world survey conducted by the World Allergy Organization, the British Society for Allergy and Immunology reported that 25 percent of the adult and 25 percent of the childhood population in the U.K. suffer from one or more allergic diseases; however, the overall prevalence of allergic disease in the U.K.'s general population has remained stable over the past 10 years.

Allergen-Related Recalls

Along with food allergies, allergen related product recalls continue to be on the rise in the European Union (EU), while in the U.S. undeclared allergens were reported as the single largest cause of food recalls, representing approximately 40 percent of recalls recorded in the third quarter of 2013 alone. According to recent quarterly recall index published by ExpertSOLUTIONS, USDA-registered product recalls increased by 33 percent in the second quarter of 2014 compared to the first quarter of the same year, with 50 percent of those recalls initiated due to undeclared allergens. These product recalls are mainly a result of simple operational errors such as failures in the review and approval of product labels; failures to load and/or change to the correct product packaging; failures to adequately review supplier information, such as supplier certificate of analysis, to spot the presence of allergens; etc. Unintentional cross-contamination is considered to be an important cause of allergen-related product withdrawals, although the majority of those recalls are a result of mislabeling and mis-packaging errors.

Prevention of cross-contamination can be achieved following different approaches listed amongst the recommended general practices: efficient cleaning of production lines and of equipment and utensils used in the product preparation and handling, strict separation of materials that may contain allergens, formal procedures for rework, and adequate personnel training programs. Publically accessible guidelines on effective allergen management and control have been published to use as a reference material. In Europe, FoodDrinkEurope published a guidance document on allergen management practices for food manufacturers in January 2013. The document provided an overview of key elements in allergen risk management, such as staff training, supplier management, raw material handling, equipment and factory design, documentation and record keeping, manufacturing processes, product development/reformulation, and consumer information. It also included some practical implementation tips, an allergen risk assessment model, and an overview of the latest European legislation on allergen labeling. In addition, the British Retail Consortium (BRC) published a new best practice guideline document on allergen management in March 2014 for food manufacturing sites that aimed to provide additional explanation of the allergen management requirements of the BRC Global Standard for Food Safety. It was designed to assist individuals and companies towards the development of robust allergen management systems and procedures that would meet the requirements of the Standard.

The Confusion

A recent industry survey carried out by SGS confirmed that although industry was familiar with the best practice approach to allergen management and control and adopted recommended practices to various extents, participants identified key knowledge gaps related to allergen labeling. Lack of a harmonized and consistent approach in allergen risk management and determination of safe allergen thresholds was identified as the top knowledge gap (67.1 percent of respondents) while a gap in knowledge around allergen cross-contamination labeling rules came third on the list (46.6 percent of respondents). Product labeling is an important risk management and communication tool and should help consumers make an informed choice about the products they are buying. There is no cure for the effective treatment of food allergies and therefore sensitive consumers would need to rely on avoidance, which is entirely dependent on the accuracy of

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A "zero threshold" approach currently adopted is far from being operationally practical or feasible.

the information included on the product label. Even though guidance exists as to what would constitute probable contamination, such guidance cannot discriminate the actual levels of such contamination that would be sufficient to elicit, or not, a reaction in sensitive individuals.

Some businesses have adopted their own levels of an allergenic food protein that they consider would constitute little or no hazard to sensitive individuals (also known as reference dose). Reference doses have then been extrapolated to derive the action levels, i.e. the concentrations of allergenic food protein within the actual product that could be considered as being safe to the sensitive consumer. A lot of work has been carried out to reach a consensus on action levels for allergens of common concern and this has been coordinated by the New Zealand and Australia Allergen Bureau that have developed what is known as Voluntary Incidental Trace Allergen Labeling system, also known as VITAL. This is a risk management tool used to determine the concentrations of a food allergen present in a food product that could trigger the adoption of precautionary labeling.

Precautionary Labeling

The first question in the use of appropriate precautionary labeling is whether such warning is actually needed. General guidance for the use of precautionary labeling was published in 2006 by the Foods Standards Agency in the U.K. in the form of a decision tree. This included a series of questions that aimed to identify the likelihood under normal operating conditions for cross-contamination of a specific food to occur with any of the allergens of concern along with the role of such allergen(s) in the product recipe and its regulatory status—is it exempt from the country's mandatory labeling or not. According to the above decision tree, if a probable likelihood for cross-contamination to occur exists, and the allergen is not already included in the product label as an ingredient and is not exempt from the mandatory labeling regulations either, i.e. it needs to be labeled if present, then hazard characterization needs to follow and the question whether the risk of cross-contamination can be managed or not answered. If the risk cannot be managed despite optimizing Good Manufacturing Practices, then a warning label, or precautionary label, is required.

The use of allergen action levels in precautionary labeling was further discussed within a recently published guidance document from Campden BRI entitled *Food Allergens: Practical Risk Analysis, Testing, and Action Levels*. According to the guide, actions levels should not be used in cases where the food allergen of concern is part of the product recipe, i.e. it is intentionally added. Instead, labeling of that allergen should be covered by the applicable legislation. The action level approach is not applicable in cases where the food containing the allergen of concern is targeted for consumption by infants or people allergic to the specific allergen; infants are generally thought to have higher sensitivity to food allergens than adults and at the same time clinical research has used observations made in adults. Action levels cannot be used in products that are labeled as free-from a specific allergen either.

Why Important

Whilst existing legislation requires food known to cause significant food allergies, when intentionally used as part of the recipe, to be declared, currently there is no legislation coving the unintentional presence of allergens in a product as a result of cross-contamination. It is for this reason that precautionary labeling has been extensively adopted by industry.

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An increase in precautionary labeling being used in an inconsistent manner across different food types has significantly impaired its intended impact as an important risk reduction warning.

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However, an increase in precautionary labeling being used in an inconsistent manner across different food types has significantly impaired its intended impact as an important risk reduction warning and therefore guidance on its appropriate use is necessary. During the 2014 Global Food Safety Conference, SGS discussed its industry survey and confirmed that lack of communication and interpretation of available guidance on the use of action levels and the implementation of precautionary labeling was a top challenge across industry. It was concluded that inconsistency in allergen risk assessment, management, and control is not necessarily a result of a specific knowledge gap in recommended practices, existing laws, or regulations governing allergen labeling. Instead such inconsistency could be attributed to uncertainty in the interpretation of such laws and regulations that would in turn affect their effective implementation.

A "zero threshold" approach currently adopted is far from being operationally practical or feasible; it is therefore practically impossible to guarantee complete removal of every single molecule of allergenic residue, especially so in facilities where a number of products of differing allergen profiles are manufactured. As a result, the use of precautionary labeling continues and will continue to be on the rise. At the same time, scientific data currently available confirm that allergen safe levels are higher than zero and that there are "thresholds" below which an allergen does not constitute a food safety hazard. Acknowledgment of the existence of population thresholds by regulators is required before the implementation of a single standard on allergen risk assessment, such as the VITAL program, is achieved as a recognized allergen labeling decision-making tool across the food industry. ■

Dr. Komitopoulou, the global technical manager for food at SGS, is a food microbiologist with specific areas of experience in microbiological risk assessment and specifications, food processing, and preservation. Reach her at Evangelia.Komitopoulou@sgs.com.

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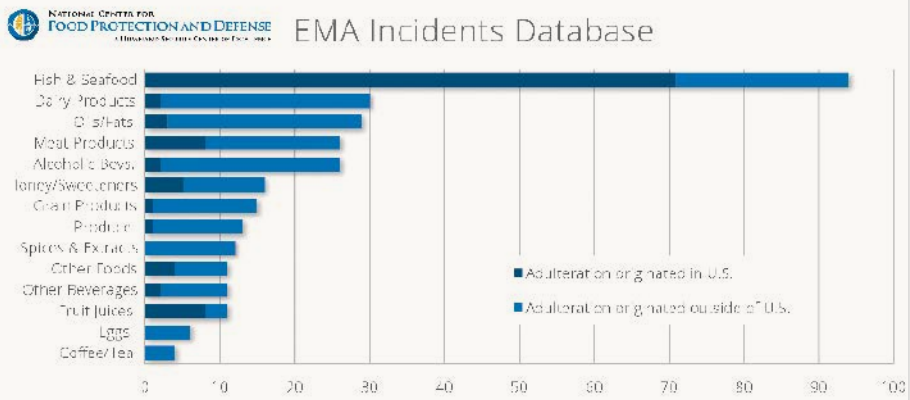

Figure 1: The number of EMA incidents in each food product category, by location of origin of adulteration.

Uncovering Product Vulnerability

Addressing the risk of economically motivated adulteration in imported foods with vulnerability assessments

BY **KAREN EVERSTINE, PHD** AND **JEFFREY MOORE, PHD**

The food supply is becoming increasingly globalized and U.S. consumers eat imported foods or ingredients on a daily basis. More than 15 percent of the foods we eat in the U.S. are imported, with as much as 80 percent of seafood products coming from other countries. Many food ingredients, such as spices, are sourced almost exclusively from other countries. The FDA estimates that importation of regulated products next year will be triple that from 2007. Globalization of the food supply increases the length and complexity of supply chains, and arguably increases the opportunity for both foodborne illness and economically-motivated adulteration (EMA). Of the more than 450,000 food and feed facilities registered with FDA, more than 285,000 are foreign facilities. There is a large gap in inspection coverage among foreign facilities and domestic facilities. Between 2001 and 2007, only 1 percent of foreign food firms were inspected by FDA. The agency has proposed a number of programs aimed at addressing the challenges posed by imported food products and ingredients. However, there is still some debate about how to approach the problem of EMA.

Types of EMA

Various groups have defined EMA, or food fraud, including the Global Food Safety Initiative (GFSI), the U.S. Pharmacopeial Convention (USP), and the Grocery Manufacturers Association, or GMA. The bottom line is that EMA involves misrepresentation of the true nature of a food product or ingredient, with the goal of the economic gain of the seller. The National Center for Food Protection and Defense at the University of Minnesota has identified the following eight types of EMA.

Substitution involves complete replacement of a food product or ingredient with an alternate product or ingredient. Examples include fish species fraud or selling olive pomace oil as extra virgin olive oil.

Dilution involves partial replacement of a food product or ingredient with an alternate ingredient. Examples include dilution of honey with sugar syrups and the addition of horse meat to ground beef.

Transshipment or origin masking refers to misrepresentation of the geographic origin of a product to avoid import duties, regulatory oversight, or to benefit from consumer demand. Examples include routing Chinese honey shipments through Vietnam to avoid U.S. import duties and mislabeling imported shrimp as U.S. Gulf coast shrimp.

Artificial enhancement is the addition of unapproved chemical additives to enhance the perceived quality of a product. Examples include the addition of Sudan dyes to chili powder and the addition of melamine to milk.

Mislabeling refers to misrepresentation with respect to harvesting or processing information. Examples include falsification of label information for organic produce, cage-free eggs, kosher foods, halal foods, and date-markings.

Theft and resale refers to situations where a food product has been stolen and re-enters into commerce through unapproved channels. Examples include retail theft of infant formula and cargo thefts.

Counterfeit is fraudulent labeling of a product by an unauthorized party as a brand-name product. Examples include counterfeit infant formula and counterfeit Heinz ketchup bottles.

Intentional distribution of a contaminated product is the intentional sale of a product despite knowledge of foodborne contamination. Examples include the intentional sale of *Salmonella*-contaminated peanut products and the intentional export of dioxin-contaminated fish.

EMA has occurred in many food products (see Figure 1). EMA incidents typically do not result in consumer illnesses or deaths since the goal of the perpetrators is to not be detected. However, perpetrators do make mistakes and are not always knowledgeable enough about the safety of the adulterants being used. Adulteration of milk supplies in China with the nitrogen-rich chemical melamine is the most recent example of EMA resulting in wide-

NCFPD EMA INCIDENTS DATABASE

spread illnesses and deaths. In 1981, thousands of people in Spain became ill and hundreds died after consuming fraudulent olive oil that was actually industrial-grade rapeseed oil.

In 1985, sweet white dessert wines imported from Austria were recalled in the U.S. and other countries due to adulteration with the chemical diethylene glycol (DEG). The addition of small quantities of DEG allowed the continuous production of desirable wines of a consistently high quality without causing short-term health effects in consumers. Ultimately, the adulteration was discovered by a tax inspector who investigated the tax records of a winery. This incident illustrates two of the biggest challenges of preventing EMA. The first is that perpetrators—in this case, a chemist—are intelligent adversaries that may have the technical expertise to effectively evade quality assurance and regulatory testing programs. The second challenge illustrated by this incident is that the most successful adulterant is the unexpected adulterant. At the time of the Austrian wine incident, there was no reason to expect the presence of DEG in wine and no testing was being done for this adulterant.

Vulnerability Assessments

For all these reasons, food companies that want to proactively address the risk of EMA in food ingredients that they source need to go above and beyond what is currently outlined in the proposed rule on preventive controls in the recently-released update to the Food Safety Modernization Act (FSMA). In the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" proposed rule, FDA indicated that additional requirements surrounding EMA would best be addressed as part of preventive controls efforts. The regulations as proposed would focus on "circumstances where there has been a pattern of adulteration in the past" and adulterants that are most likely to cause illness. Relying only on these factors would likely not have prevented the tragic melamine incident of 2008 given the lack of historical information about melamine adulteration of dairy products that was available at the time. There is general consensus among many organizations that effective mitigation of EMA requires a vulnerability assessment type of approach that holistically considers several contributing factors that underlie the opportunity and incentive for perpetrating EMA instead of just focusing on historical incidents. The GFSI Food Fraud Think Tank recommends the food industry conduct vulnerability assessments and subsequently put in place appropriate control measures.

On Nov. 17, 2014, USP, a scientific standards-setting organization that develops quality standards for medicines, food ingredients, and dietary supplements, issued the first publicly-available draft guidance on conducting EMA vulnerability assessments. The draft guidance for mitigating EMA risk was designed to be generally applicable to any food ingredient, and any food fraud management system that can be developed from this framework should be viewed as a dynamic and con-

(Continued on p. 26)

	Contributing Factor	Contribution to Vulnerability: Low[a]	Medium-Low[a]	Medium[a]	Medium-High[a]	High[a]
Controllable factors	Supply chain	Firm vertically integrated	Supplier vertically integrated	Supplier manufactures	Upstream supplier manufactures	Open market
	Audit strategy	Robust, onsite, with numerous anti-fraud measures	Robust, onsite, with limited anti-fraud measures	Immature, onsite, no antifraud measures	Currently developing an onsite audit strategy	No onsite audits
	Supplier relationship	Trusted supplier and previously purchased ingredient(s)	Trusted supplier and new ingredient	Established supplier and some relationship	Established supplier and no prior relationship	Unestablished supplier and no prior relationship
	History of supplier quality & safety issues	No known issues	Few minor issues, quickly resolved	Recurrent issues or resolution concerns	Multiple persistent issues; some evidence of inadequate controls	Strong evidence of quality or safety concerns; inadequate controls
	Testing frequency	Intensive-every lot independently tested by buyer	Random lots independently tested by buyer	Independent testing done at yearly or other limited intervals as part of supplier qualification	No independent testing done, reliance on Certificate of Analysis	COA either not present or not specific to lot/shipment. No independent testing
	Susceptibility of QA methods and specs	Methods are very selective/specific; specifications only allow for natural variability.	Methods are selective/specific; specifications allow for natural and analytical variability.	Methods are selective but not specific; specifications reflect same.	Methods are of limited selectivity/specificity; specifications reflect same	Methods are not selective or specific; specifications ranges are broader than ideal
Uncontrollable factors	Geopolitcal consideratons	Ingredient is a single component sourced from a single geographic origin of low concern	Several components sourced from geographic origin(s) of low concern	Single component; originated or transited through regions with some geopolitical concerns	Several components; some originated or transited through regions with some geopolitical concerns	One or more components originated or transited through one or more regions exhibiting several characteristics of geopolitical concern
	Fraud history	No or few known reports; no substantiating evidence	Moderate volume of reports; no substantiating evidence	Numerous reports; limited substantiating evidence	High volume of reports; some substantiating evidence	High volume of reports; good substantiating evidence
	Economic anomalies	Nothing unusual	Isolated anomalies	Frequent but unrelated anomalies	Common but focused anomalies	Common and broad anomalies

[a]Vulnerability category descriptors in this table are significantly simplified for purposes of this introduction. Users should consult the corresponding factor section later in this document for a more complete description of these categories

Table 1: Framework for conducting an EMA vulnerability assessment. Each contributing factor to EMA vulnerability should be evaluated separately in terms of its contribution to overall vulnerability of a food ingredient.

(Continued from p. 25)

tinuous process. The guidance includes an assessment of the contributing factors to EMA vulnerability, which can then be ranked on a low-to-high scale for vulnerability (see Table 1). Each of these contributing factors is discussed briefly below.

EMA/Food Fraud History. One of the most basic indicators of EMA vulnerability in a particular food product or ingredient is its EMA history and pattern. Information about EMA incidents and issues can be found in the NCFPD EMA Incidents Database and USP's Food Fraud Database.

Supply Chain Structure. Visibility and control along supply chains can mitigate EMA vulnerability. The degree of vertical integration, oversight, and traceability should all be considered as part of a vulnerability assessment.

Supplier Relationships and History of Quality/Safety Issues. In addition to the structure of supply chains, the degree to which an established and trusted relationship has been formed with ingredient suppliers and the history of food quality and safety issues among those suppliers can provide insight into the potential for EMA vulnerability.

Susceptibility of QA Methods and Specifications. EMA perpetrators are often very familiar with industry standard QA methods and specifications. Therefore, it is important to consider how effectively the suite of methods and specifications that are incorporated into a QA program can characterize an ingredient and detect inauthentic ingredients.

Audit Strategy. The rigorousness of the audit strategy and the inclusion of anti-fraud measures in audits are an important consideration when assessing the vulnerability of a food ingredient to EMA.

Testing Frequency. The frequency used to test raw materials entering a food processing facility is an important factor in EMA vulnerability. Evidence-based testing reduces EMA vulnerability by increasing confidence in the integrity of raw materials and helps to establish trust in suppliers.

Geopolitical Considerations. U.S.-based food companies and consumers are reliant upon the food safety and regulatory systems in other countries when importing food products. Therefore, it is recommended to include a consideration of the level of development of the food safety and regulatory system and other relevant factors such as system disruptions and corruption indices for the geographical source of the ingredient, as well as geographic locations through which it is transported.

Economic Anomalies. Since EMA is motivated by the potential for economic gain, monitoring of various forms of economic data may help provide insight into increased vulnerability to EMA in a particular food commodity or ingredient. This may be either macro-level or micro-level data, depending on what is accessible to the organization conducting the vulnerability assessment. One example is the sharp increase in global vanilla prices beginning in 2000, and corresponding evidence of vanilla fraud during the same time period.

The horse meat adulteration incident resulted in a 1 percent drop in sales for one U.K.-based grocery chain, followed by a 5 percent drop in shares. In addition to the cost to companies, EMA threatens the health of consumers, has negative effects on markets, and causes brand damage. Food companies that have a vested interest in protecting their brand will need to adopt proactive programs to address EMA that go beyond traditional food safety measures. ■

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Food standard authorities rely on food laboratories to use sophisticated instrumentation and techniques to identify components of foodstuffs.

Intercepting Food Fraud Before It Hits the Shelves

Techniques to identify the authenticity and purity of products are in demand as more counterfeit foods enter the consumer supply chain | BY **STEPHEN HARRISON**

The economic impact of counterfeiting products in the food and beverage industry amounts to millions in lost sales and profits to retailers, producers, and suppliers. Fake claims about the content of foods and beverages also pose an unsuspected risk to consumer health, as well as to people who base their food choices on their ethical and religious convictions.

Consequences

Consumers make their purchases in good faith, putting their confidence in the honesty and integrity of the supply chain. Counterfeiting is at odds with this reasonable assumption that a product is all that it claims to be on its labeling. Coinciding with the financial losses facing businesses on the production and supply side, the consequences to consumers can range from simply being deceived about the product's content, or not benefitting from the anticipated efficacy of the product, to the more severe outcomes, including illness and death.

The world was made aware of this danger in 2008, when six babies died and 300,000 babies fell ill after drinking melamine-tainted milk products in China. Another major food scandal broke in Europe in 2013, when it was revealed that horse meat was being labeled as beef from cattle. Although horse meat is suitable for human consumption, the public health issue relates to the type of tests conducted to prove the suitability of the beef for human consumption. Since these tests differ from those applied to horse meat, applying the wrong tests to the sample could create an opportunity for hazardous substances, such as residual chemicals from veterinary medicines, to enter the food supply chain.

Food and beverage counterfeiting syndicates are motivated by greed and driven by the attraction of increased sales margins. Sometimes a reluctance to discard products that have passed their sell-by date leads to re-labeling and, in the case of exported products, there is an objective to bypass or reduce Customs and Excise duties on certain premium products.

Commonly Counterfeited Products

Despite the best efforts of national food safety authorities such as the U.S. FDA and the European Food Safety Authority, certain food and beverage product types continue to fall prey to counterfeiting. Notable examples include olive oil, goat's milk, wines, basmati rice, honey, caviar, vanilla, and saffron.

Olive oil is product that is produced to different standards by varying methods of production, and its quality is also determined by the free acidity of the soil. The production and sell-by dates are also important because olive oil eventually oxidizes and becomes rancid. Since each of these factors determine the value of the end product, falsifying any of this information amounts to counterfeiting. In a similar vein, a variety of aromatic basmati rice types are sold at premium prices on the world market, and the increasing value consumers are placing on this product also makes it a prime target for counterfeiters who adulterate the product with the addition of cheaper types of long grain rice. The average consumer, recognizing the distinct aroma of the basmati rice, would probably not notice the presence of the other type of long grain rice.

Goat's milk can be diluted with cow's milk and the difference is very difficult to detect by taste alone. Honey can be counterfeited in various different ways. It can be adulterated with sugar, corn syrup, and other sweeteners, or the type of honey is misrepresented by a fake declaration of botanical or geographical origin to attract a higher price on the market. For example, Manuka honey is broadly hailed as a wonder product that demonstrates antiviral and antibacterial qualities. Not as sweet as normal honey, it is made by bees gathering nectar from the delicate flowers of the Manuka bush, native to New Zealand. When this rare and highly priced product is misrepresented, consumers are not only duped financially, but are also cheated of the health benefits associated with it. Caviar is another rare and expensive product that black market dealers substitute with the roe of other fish, passing it off as the roe of the sturgeon harvested only in the waters off Russia and Iran.

Expensive spices like saffron and vanilla are also frequently faked by being

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synthetically produced or by being substituted with cheaper spices that taste and look the same thanks to food flavoring and dyes. Saffron is the world's most expensive spice, originating from a relatively rare crocus flower that tends to produce only about four blossoms in its lifetime. It is often counterfeited with other harmless plants, such as calendula or even dried onion that has been dyed orange. Saffron and vanilla are grown in many countries where a cash crop is sorely needed and one of the consequences of counterfeiting is to rob such communities of a percentage of their livelihood.

Wines and brandies also lend themselves to counterfeiting through false information on the labeling, particularly since certain vintages attract far higher prices than others. Counterfeiting in this realm includes adulterating these liquors with the addition of cheaper products such as fruit juices, and sometimes with the addition of harmful chemicals and sweeteners to compensate for color or flavor.

Over and above the issues of public health, fraud, and tax evasion, counterfeiting of food impacts the spheres of ethics and religion. Many consumers choose to avoid foods that contain beef, pork, or other ingredients derived from animals, and falsely labeled foodstuffs deceive them into transgressing these principles.

Prevention

The increasing penetration of counterfeit food and beverage into the consumer supply chain is prompting authorities to accelerate existing measures to intercept and identify these products. For example, during 2013, Customs and Excise laboratories in France ran half a million analytical tests last year on wines and beers entering the country, bringing the role of scientific analysis into sharp focus. Counterfeit goods are invariably undetectable by sight and smell alone and therefore samples of suspect goods must be analyzed using sophisticated chemical analysis techniques.

Food standard authorities typically rely on expert food laboratories, which use sophisticated instrumentation and techniques to identify components of foodstuffs. One of the most commonly used techniques involves gas chromatography where the food sample to be tested is first turned into a gas, and then carried through a column by a nonreactive "carrier" gas, or a gas that will not impact the integrity of the food sample, such as helium or another other inert gas like nitrogen. As the sample is carried through the column, it is separated into its individual components. The separate components can then not only be identified, but how much of each component present is can also be determined.

Despite its name, liquid chromatography also employs gas to analyze foodstuffs. The food sample is dissolved into a solvent (hence the "liquid") and then carried by a moving gas stream (helium or nitrogen) to breakdown the sample into individual constituents. Liquid chromatography's even more sophisticated cousin, high performance liquid chromatography (HPLC), can also help identify compounds as low as parts per trillion.

When more sophisticated analysis is required, a technique known as Nuclear Magnetic Resonance (NMR) can be used. This advanced technique for food counterfeiting investigations involves generating a very high magnetic field around the nuclei in a particular molecule to allow the nuclei to absorb and re-emit electromagnetic radiation. The pattern in which this occurs is detected to identify which particular molecules are present. The intense magnetic field is generated by a super-conducting magnet that can only operate in extremely cold temperatures. This is achieved by immersing the electro-magnet in liquid helium—the coldest substance on the earth.

In all these techniques, high purity specialty gases, which do not interfere or contaminate the food sample in any way, play a critical role.

The authenticity of olive oil can be established to a high degree of certainty by analyzing the most frequently occurring chemical components and developing a "fingerprint" for a particular product. The technique most likely to be used to conduct this sophisticated fingerprinting and profiling of olive oil is NMR.

One of the most reliable techniques for determining the age of a wine or a brandy is looking at the quantity of carbon isotope that exists in these liquors. This method uses radioactive carbon isotopes left in the atmosphere by atomic bomb tests carried out about 50 years ago, as well as from the burning of fossil fuels and volcanic eruptions. NMR is also used to conduct this analysis to determine the vintage of a wine quite accurately.

To determine whether caviar is truly from a sturgeon or another type of fish, analysts examine the product's DNA, the unique marker of a species. Sometimes enhanced with fluorescent dyes, samples can be examined by a photo spectrometer or, if more sophisticated test is required, the NMR is once again brought into play. DNA testing is also proving an effective way to identify the authenticity of basmati rice, since rice varieties have different DNA fingerprints.

After saffron, vanilla is the world's most expensive spice, and some manufacturers add coumarin to vanilla products to increase the vanilla flavor perception. Coumarin is a phytochemical found in many plant species, the main source being the tonka bean. It has a sweet herbaceous odor and has been used in food, tobacco, and cosmetics as a flavoring and fragrance material. However, coumarin has been shown to be damaging to liver cells, and has been prohibited from being added to food in the U.S. since 1940. Liquid chromatography, HPLC, and even ultra-high performance chromatography (UHPLC) have proved to be effective scientific methods to determine the presence of coumarin in vanilla extract products.

The demand for the specialty gases that facilitate the detection of ever lower levels of chemicals in food is on the increase. For example, Linde offers the food industry a range of high purity specialty gases that include nitrogen and helium for gas chromatography mass spectrometry, nitrogen for liquid chromatography mass spectrometry, liquid helium for NMR, and helium gas for HPLC and UHPLC.

However, the integrity and purity of the gas is only as good as the equipment that delivers it to the point of use. For instance, Linde says it can ensure its gases are delivered to the instrumentation without comprising their quality—often up to a purity level of 99.9999 percent—through its specialty gases equipment. ■

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The Rise of Product Diversion and Counterfeiting

Serialization and tracking and tracing have potential to reduce counterfeit products in food and beverage as well as the pharmaceutical supply chains | BY **BARRY MCDONOGH**

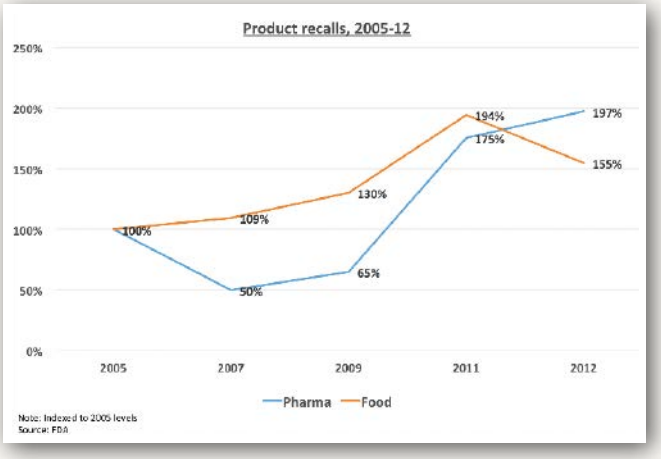

Figure 1: The rise in external product failures as represented by the number of recalls recorded by the FDA in the food and beverage/pharmaceutical sectors.

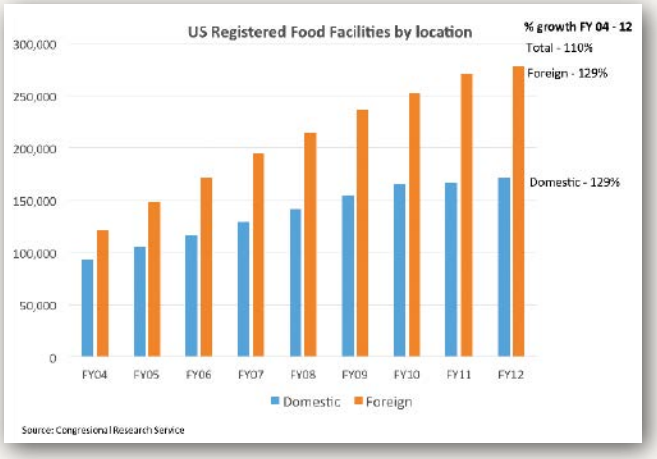

Figure 2: The growth in the number of registered food facilities that are potentially subject to FDA inspection.

Internationalization and the emergence of new business models has increased the complexity of the food and beverage supply chain. The rise in complexity has resulted in a loss of supply chain visibility and control, which in turn has led to mounting product quality and safety challenges. This article draws parallels between the food and beverage and pharmaceutical industry to illustrate that traditional efforts focusing on the internal quality of manufacturing are no longer sufficient to safeguard consumer safety.

The food and beverage and pharmaceutical industries share many commonalities. One similarity is the importance of product safety, where an external quality failure can represent a serious threat to consumer well being. As the supply chains of both industries have become increasingly globalized, they have faced escalating incidents of external quality failure. The root causes of these failures can be classified into two broad categories: *internal*—relating to manufacturing, and *external*—relating to the distribution chain.

As markets become more competitive, corporations across the world are driven to outsource and offshore manufacturing as a means of sustaining profitability. A consequence of these practices is a corresponding decline in quality performance.

Combatting Internal Challenges to Product Quality

Both the food and beverage and pharmaceutical industries have taken similar approaches to strengthen internal quality management through the implementation of current Good Manufacturing Practices as a means of governing the manufacture, processing, and holding of product. Irrespective of whether production is domestic, offshored, or outsourced, manufacturers are still required to utilize facilities that comply with all FDA regulatory requirements.

While quality standards have been set, a real problem has arisen in the capacity of the FDA to monitor site compliance. The number of registered food facilities has more than doubled in the period FY 04-11 with an ever-growing proportion of these sites located abroad. In 2011, the FDA inspected 318 international food manufacturing locations, equating to a little more than 0.1 percent of the 271,272 registered sites. While legislation such as the Food Safety and Modernization Act (FSMA) has attempted to address this issue by increasing the planned number of inspections to roughly 20,000 by 2016, this would still represent just 7 percent of 2011 facility numbers.

The FDA faces a similar problem within the pharmaceutical sector and has recently gone as far as increasing the annual facility fees on foreign manufacturing sites as a means of funding the rising cost of foreign inspections.

With an estimated 15 percent of the U.S. food supply, 80 percent of active pharmaceutical ingredients, and 40 percent of finished pharmaceutical drugs now being imported from abroad, the problem of managing quality in foreign locations is one that the FDA will have continuing difficulty in governing.

Manufacturers, insurance companies, and vendors can support regulatory efforts through diligent, conscientious procurement and stringent supplier selection and management. However, even the achievement of internal quality management standards

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in outsourced and offshore facilities is in itself insufficient to safeguard consumers, as globalization has also produced external threats to product safety in the distribution chain.

External Threats to Product Safety

The problems in the external distribution chain are both insidious and difficult to control. Here, the increasing complexity of the supply chain has facilitated the rise in both product diversion and counterfeiting.

Diversion relates to the transfer of authentic product from its intended point of distribution with an aim to capitalize on arbitrage opportunities. While not necessarily illegal, diversion can compromise product integrity if the affected goods are not appropriately stored.

Counterfeit goods are fraudulent or adulterated imitations represented as genuine product that may pose a grave threat to consumers as they are produced with little concern for quality or safety standards.

Food and Beverage Counterfeits

Valued at a staggering $49 billion dollars a year and growing, the counterfeit food and beverage market presents a significant risk to consumer safety. The counterfeits enter the market by a number of different means. One ploy is to present cheap versions of products as higher quality brands. A second is to introduce cheaper ingredients into authentic products in order to increase profit margins. In both cases the risk to consumer safety is significant.

The U.S. Pharmacopeia Convention, or USP, is the global watchdog group whose food and pharmaceutical standards are enforceable by the FDA. It has logged more than 2,000 incidents of food fraud, impacting a wide variety of food and beverages. Notable cases include the following:

- More than 1,200 tons of fake/substandard food and nearly 430,000 liters of counterfeit drinks were seized as part of Interpol/Europol operation in 2014;
- In 2013, multiple instances occurred in the European meat supply chain where horse meat was presented as beef;
- In 2012, 20 people died in Czech Republic and many others hospitalized and blinded after consuming fake liquor that contained methanol; and
- A two-year study of U.S. fish supplies concluded in 2012 that approximately 33 percent of the 1,215 samples analyzed nationwide were mislabeled.

Counterfeits in Other Industries

The incidence of counterfeiting of pharmaceuticals has also grown dramatically in recent years. While the counterfeit products may look the part, the reality is far from that. They are regularly manufactured in squalid conditions with the incorrect formulation, dosage, or no active pharmaceutical ingredient at all. Some counterfeit pharmaceuticals have been even found to contain household cleaners, heavy metals, and poisons.

The World Health Organization estimates that in the developing world counterfeit drugs can account for between 10 and 30 percent of the market. In developed economies, approximately 1 percent of drugs are counterfeit.

Combatting External Threats

One technique utilized to counteract the problem of counterfeiting and diversion involves the serialization and tracking and tracing of products (STT).

The STT model is predicated on using a product's origin as a means of preventing counterfeits from entering supply chain. By assigning unique numbers to each product and introducing authentication at various points, the potential for counterfeit products to get through the supply chain undetected is substantially reduced. STT systems also provide improved supply chain visibility so that instances of diversion can be identified and corrected.

The STT architecture is typically comprised of three elements: a method of marking products with a unique number either through direct part marking or on packaging—typically achieved through barcoding or RFID technology; scanning infrastructure to capture specific events related to product movement within the supply chain; and a means of analyzing and reporting on these captured events.

The STT system is considered one of the most effective in combatting counterfeiting and diversion. So much so that pharmaceutical regulators across the world are in various stages of completion in terms of rolling the systems out.

STT in the U.S.

To ensure authenticity as products change custody within the supply chain, the FDA requires all pharmaceutical products sold in U.S. to be serialized and scanned at a unit or aggregate level through the Drug Supply Chain Security Act by 2023.

However, there is no such unifying framework in place for the food and beverage industry. In fact, a recent comparison of global food traceability regulations and requirements focusing on 21 industrialized countries found that the U.S. trails behind most other nations analyzed in terms of basic food traceability.

While no comprehensive traceability standards have been proposed to date, some market segments such as infant formula have begun to lay the foundation. In June 2014, the FDA revised the Infant Formula Act of 1980 to tighten the controls related to internal quality assurance. One provision was the requirement to serialize production to enable traceability.

On a macro scale, FSMA references the requirement for enhanced product tracing abilities going forward. The Institute of Food Technologists (IFT) has also completed pilots that demonstrate the value and achievability of such systems.

The ever-increasing threat to consumers posed by counterfeiting, coupled with the work of advocacy groups like IFT, is likely to drive more action from the FDA.

The Future

In the near future, consumers can expect to self-verify that the food in their hands is safe for consumption. To achieve this goal, manufacturers will be required to make investments beyond traditional internal quality assurance and protect against the external threats outlined in this article. The technology to do this already exists and is being utilized in other industries.

As manufacturers make investments in STT systems, they will find that the ROI goes far beyond defensive positioning and the technology can be used to solve real business problems and even offer a means of competitive differentiation. ■

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REFERENCES FURNISHED UPON REQUEST

Testing

SEAFOOD

Crustacean Residues in Foodstuffs

An increasingly widespread issue in regards to food allergies, crustacean test methods must be very specific and detect minute quantities of allergen in complex food matrices

BY **LILIAN KUSTER**

Nowadays, seafood plays a very important role in human nutrition worldwide. It is among the major foods consumed globally, mainly due to a large movement towards healthier eating. International trade in seafood and new seafood products is growing rapidly and there are more and more reports of adverse reactions in the population consuming seafood. The generic term "crustaceans" includes all arthropodic aquatic animals, with six major subgroups and 44,000 species. Hidden crustacean proteins in food represent a critical problem for people with crustacean allergies. Sufferers have to avoid the consumption of food containing crustaceans very strictly. Still, cross-contamination can occur as a consequence of the production process.

International organizations, such as the Codex Alimentarius Commission of the World Health Organization, or WHO, and the Food and Agriculture Organization, or FAO, have discussed a labeling system for allergenic ingredients in processed food and labeling is now recommended for eight food groups, including crustaceans. In the European Union, there are different regulations that establish labeling must be present in regards to the main types of food allergens to warn consumers. In the U.S., the Food Allergen Labeling and Consumer Protection Act of 2004 includes the eight major allergen groups—namely milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. However, allergens can be present in the final food product even though the ingredients are not allergens due to cross-contamination between raw materials, equipment, or production lines. Therefore, there is increasing need for sensitive detection of crustacean residues in foodstuffs, as well as diagnosis and treatment of seafood allergies to protect the allergic consumer and to ensure supervision of labeling requirements by the authorities responsible.

Allergy Overview

Food allergies in general have become an important health problem and represent a food safety issue. Food allergies, defined as an adverse immune response to food proteins that the human body mistakenly identifies as harmful, affect approximately 5 to 8 percent of children and 2 to 3 percent of adults in developed countries, with rising prevalence. A true allergic reaction is defined as a type-one hypersensitivity activating a specific type of white blood cells, the mast cells, leading to an immunoglobulin E response. Histamine and inflammatory mediators, such as cytokines, are released, leading to different symptoms, including itchiness, gastrointestinal disorders, dyspnea, or even anaphylaxis and death.

Crustaceans are among the eight food groups thought to lead to allergies triggered by immunoglobulin E antibodies worldwide. Hypersensitivity reactions to different ingested crustaceans, including shrimps, crabs, lobsters, and others are among the most frequent causes of food allergic reactions. Furthermore, crustaceans are the third most important foodstuffs inducing food-related anaphylaxis. Several studies have shown that even minute amounts of ingested seafood allergens can trigger very quick allergic reactions. It is assumed that even inhaled airborne allergens can lead to sensitization and allergic reactions. Very commonly, crustacean allergies appear at later stages of life and the likeliness of them being outgrown, as it is very often the case in childhood allergies, is very small.

Crustacean Allergen

The major allergen in shrimps and other crustaceans is the ubiquitous muscle protein tropomyosin, which is responsible for ingestion-related allergic reactions. It is a highly conserved protein, is homologous in different species, and shows a considerable rate of identicalness. Its high cross-reactivity even to insects like house dust mites means tropomyosin is considered as a possible cause of cross-reactivity between food and respiratory allergens of animal origins. There are other allergens that have been identified in crustaceans in the past few years, including arginine kinase and myosin, but they have not yet been characterized completely. In contrast to other seafood allergens, tropomyosin seems to be relatively resistant to acidic digestion and heat. The heat stability makes this protein suitable for the analysis

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of crustacean residues in processed food samples. Therefore, allergen-specific detection assays in food products are available for crustacean tropomyosin.

Detection

The detection methods for food allergens, including crustacean protein, have to be very specific and must detect minute quantities of allergen in very complex food matrices. At present, there are qualitative and quantitative test methods for crustacean residues available. Few techniques detecting crustacean protein, actually tropomyosin, are available, including immunological methods based on a specific antigen-antibody reaction, such as lateral flow assays and enzyme-linked immunosorbent assays (ELISA), as well as DNA-based methods such as polymerase-chain reaction (PCR) technologies, mainly real-time PCR.

Lateral flow assays are a simple and rapid detection method for the qualitative detection of crustacean residues in food, as well as rinse water and environmental samples, including surface swabbing, in production facilities. Real-time testing using on-site lateral flow methods is very important, allowing for quick testing and immediate decision making needed when a fast turnaround or trouble shooting is necessary. Lateral flow tests require few skills and only a minimal amount of training. The detection method is based on an antibody-antigen reaction. In a food sample containing crustacean residues, antigens will bind to antibodies of the test solution. A test strip being soaked into the solution after the binding reaction can be read immediately after a very short incubation time, with one line in the result zone indicating a negative result or two lines a positive result. Lateral flow assays for the detection of crustacean residues in food are rapid, simple, and require no sophisticated procedures or expensive equipment, making them suitable for routine applications, e.g. for monitoring food production lines and equipment in food processing facilities. Though these lateral flow tests are reliable, they are only qualitative, meaning the result shows that either tropomyosin is present (positive, a test line will appear) or tropomyosin cannot be detected (negative, no test line will appear). Thus, lateral flow devices are most often used as quick screening tests for checking the cleanliness of production lines and production equipment, therefore preventing one source of contamination in the final product.

In a food sample containing crustacean residues, antigens will bind to antibodies of the test solution.

The final product can be screened with a lateral flow device as well, but most often food producers prefer to carry out a quantitative method. Currently, two methods are mainly used for quantitation of crustacean protein in food stuffs: ELISA and PCR.

The ELISA is the main immunological method used for the quantitative detection of allergens in different matrices. For quantitative analysis of shellfish protein, especially tropomyosin, the quantitative sandwich ELISA—a very specific and precise assay—is widely used. Commercial test kits are available, offering limits of detection of around 0.5 to 1 milligram (mg) crustacean protein, depending on the matrix. Wells of a microtiter plate are precoated with polyclonal or monoclonal antibodies directed against tropomyosin. An extracted food sample is applied to these wells leading to the binding of tropomyosin to the antibodies. During the next step, the reaction with an enzyme-conjugated secondary antibody directed against tropomyosin leads to a complex formation that can be visualized by the development of a colored reaction product between the particular substrate and the conjugated enzyme on the secondary antibody. As an ELISA easily can be used on a routine basis, demonstrating high precision, it is probably the most utilized method for the detection of food allergens, as well as crustacean residues.

DNA-based methods, as traditional PCR and real-time PCR, detect the genome of the allergenic food as a surrogate for allergenic proteins. Therefore, the extracted DNA is amplified by polymerase chain reaction and detected afterwards (traditional PCR) or simultaneously (real-time PCR).

Testing Issues

It must be stated that both methods, ELISA and PCR, have their advantages and disadvantages and that there is no single method fulfilling all needs. An advantage of PCR is that DNA molecules are more heat stable than proteins, which allows analysis of highly processed foodstuffs. Moreover, DNA extraction is more efficient than protein extraction in difficult food matrices and harsh laboratory extraction conditions can be applied, as DNA is less prone to damage than proteins.

The main disadvantage of PCR is that the protein that causes the allergic reaction is not detected itself. Even if the presence of DNA implied the presence of protein—how could someone convert a DNA copy number to mg allergenic protein? Without knowing the expression level of a certain allergenic protein in a certain matrix, this conversion is almost impossible. For crustacean allergen analysis, normally mitochondrial genes are used as DNA targets as they are present in high copy numbers, resulting in the increased sensitivity of the assay. Again the downside is how someone can convert copy numbers into mg allergenic protein. Currently, only gluten and sulfites are officially regulated by threshold levels stating mg/kilogram concentrations. But how could someone comply, if threshold levels for all the other regulated allergens were introduced?

In general, testing issues are mainly represented by the strongly varying matrices that have to be tested (matrix effect). The detection limit of any test, therefore, will vary depending on the sample matrix to be analyzed. Although providers of test kits often have a validation protocol to be submitted with the test kit upon request, laboratories using commercial test kits must establish in-house controls on detection limits and quantification limits in actual matrices. As there are no reference methods and no certified reference materials for allergens available, one has to keep in mind that results are not necessarily comparable between different test systems. Accredited methods should be used in official controls. The National Food Agency is accredited for the analysis of shellfish protein in foodstuffs. ■

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Pesticides in Imported Produce

Rapid pesticide analysis for fruits and vegetables by using gas and liquid chromatography coupled mass spectroscopy

BY **JOE ANACLETO**

Monitoring pesticide residues in fruit and vegetables remains a key priority for international food safety. Increasing imports from countries, such as China and India, with substantially different regulations to their Western counterparts, highlights the need for stringent pesticide monitoring. Tandem mass spectrometry coupled to chromatography systems, such as gas chromatography mass spectrometry (GC-MS) and liquid chromatography mass spectrometry (LC-MS), operating in multiple reaction monitoring (MRM) mode has emerged as the industry standard for monitoring residues in fruits and vegetables. However, a continuing challenge in multi-residue analysis is finding a sample preparation method that is as easy, fast, and cost-efficient as possible.

The U.S. FDA recommends the QuEChERS (Quick, Easy, Cheap, Effective, Rugged, and Safe) method for residue screening based on MRM with advanced gas or liquid chromatography coupled mass spectrometry systems. However, these QC methodologies can be complex and time consuming, particularly for trace pesticide analysis in complex biological matrices. A modified QuEChERS preparation protocol developed by the FDA Irvine laboratory in California can extract multiple classes of pesticides from a wide variety of samples. This methodology presents an alternative to the conventional QuEChERS technique and allows the extracted matrix to be directly injected into the instrument, saving preparation time. This article demonstrates that the modified QuEChERS sample preparation protocol is a simple, less expensive, and unified alternative to conventional QuEChERS protocol.

Challenges of International Trade

The liberalization of global trade has greatly benefited emerging economies around the world. Following its accession to the World Trade Organization in 2001, China is now a major global producer of agricultural products, especially fruits, vegetables, rice, and pork. In 2009, China was the fourth leading global agricultural exporting country (behind the U.S., Brazil, and Canada), with exports to the U.S. alone reaching approximately $3.3 billion in 2010. However, the lack of global standardization or global consensus on the use of pesticides is a barrier that limits producers from accessing the full potential of the export market. Imports from regions where pesticide use is less restricted to those with stringent regulations are frequently subject to detention and often returned to their country of origin or disposed of, resulting in an immediate loss in investment.

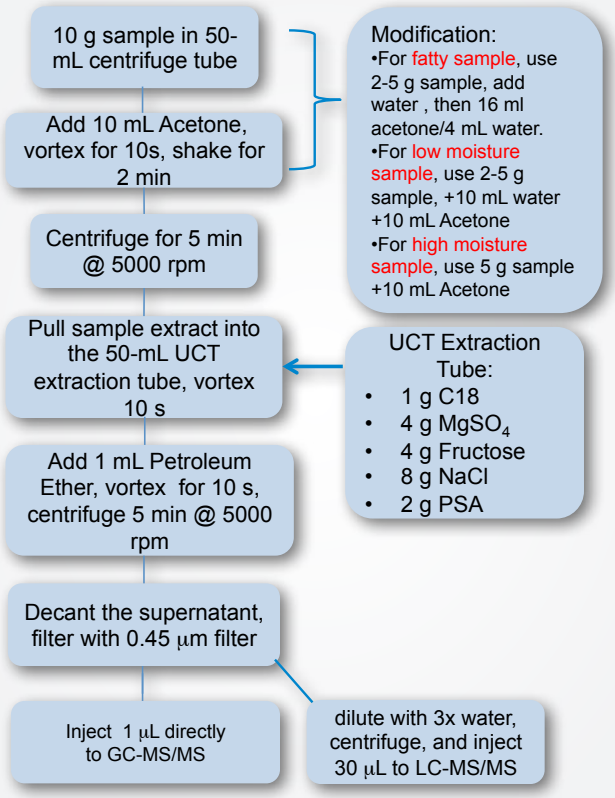

Figure 1: A modified QuEChERS sample preparation protocol developed at the U.S. FDA Lab at Irvine.

The benefits for global standardization have now been recognized and governments around the world are beginning to take steps to bring the regulations guiding crop growth and maintenance in line with their Western counterparts. For instance, China has recently limited the use of harmful pesticides that are widely banned on international markets, while Pakistan has announced its intention to bring rice and mango production in line with FDA guidance. However, accurate and robust pesticide quantification methods are essential to determine whether consumable products comply with international and domestic regulatory standards.

Extracting multiple pesticide species from fruits and vegetables is a challenging process due to the complex biological matrices. Conventional analytical techniques have, until recently, been unable to deliver the sensitivity required to achieve reliable trace

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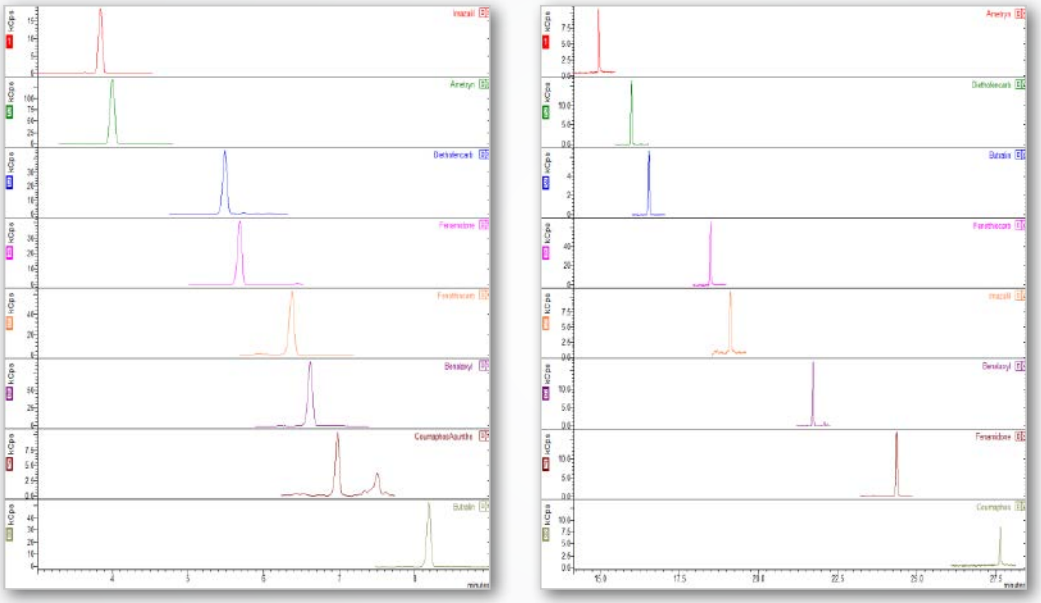

Figure 2a (left): MRM chromatograms for selected pesticides at 1 ppb in spinach extract by LC-MS/MS; Figure 2b (right): MRM chromatograms for selected pesticides at 5 ppb in spinach extract by GC-MS/MS.

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level analysis. Consistently achieving the high levels of sensitivity required can also be a time intensive and laborious task, which is undesirable for a high-throughput routine QC laboratory. Developing analytical technologies and screening methodologies to be able to quickly and accurately qualify and quantify trace pesticide residues is therefore a priority for both instrument developers and regulatory bodies.

Advancing Detection Procedures

The USDA QuEChERS method for pesticide residue analysis was presented at the 2002 European Pesticide Residue Workshop. QuEChERS simplifies the analysis of pesticide residues in food products, including fruits and vegetables, and takes advantage of advances in LC-MS and GC-MS. The method is now standardized within AOAC 2007.01 EN15662, having proven more productive than conventional preparation techniques.

The QuEChERS protocol uses less expensive and fewer solvents and provides a faster extraction method. Samples are homogenized via blending before centrifugation and extraction with a suitable reagent. The modified QuEChERS methodology developed by the U.S. FDA laboratory in Irvine presents an even simpler alternative to the conventional QuEChERS technique, allowing the extracted matrix to be diluted and injected directly into the GC/LC-MS to save further time.

Advances in both GC-MS and LC-MS have led the U.S. FDA to recommend them as the platform for QuEChERS screening. Modern LC-MS systems are generally considered to be more powerful and are able to separate a greater range of pesticide products. However, where routine detection of known volatile analytes is required, GC-MS systems are a suitable and lower priced alternative.

Despite the increased availability of sophisticated GC-MS and LC-MS systems, the functionality of many commercially available systems is still limited by technological aspects, struggling to deliver the levels of sensitivity and specificity required. Yet, triple quadrupole MRM overcomes many of these limitations and delivers the performance levels required for pesticide detection.

Technological Developments in GC-MS and LC-MS

MRM helps to maximize reliability in pesticide detection by fragmenting ionized analytes into multiple ions. When MRM is in-

Compound name	GC-MS /MS		LC-MS /MS	
	MRM 1 (eV)	MRM 2 (eV)	MRM 1 (eV)	MRM 2 (eV)
Ametryn	212 > 94 (20)	212 > 122 (10)	228 > 186 (17)	228 > 68 (30)
Azaconazole	217 > 173 (15)	217 > 145 (25)	300 > 159 (15)	300 > 231 (15)
Azoxystrobin	344 > 156 (35)	344 > 329 (10)	404 > 372 (14)	404 > 344 (23)
Benalaxyl	206 > 162 (10)	206 > 132 (18)	326 > 148 (24)	326 > 208 (15)
Bromacil	205 > 162 (15)	205 > 188 (15)	261 > 205 (12)	261 > 188 (25)
Butralin	244 > 132 (20)	266 > 190 (10)	296 > 222 (15)	296 > 240 (12)
Carboxine	235 > 87 (20)	235 > 143 (20)	236 > 143 (16)	236 > 87 (27)
Clomazone	204 > 78 (30)	204 > 107 (20)	240 > 125 (23)	240 > 89 (30)
Coumaphos	362 > 109 (15)	362 > 226 (15)	363 > 227 (20)	363 > 211 (28)
Diethofencarb	267 > 197 (15)	267 > 225 (10)	268 > 180 (15)	268 > 226 (5)
Diniconazole	268 > 171 (20)	268 > 232 (10)	326 > 148 (23)	326 > 208 (14)
Fenamidone	238 > 103 (20)	268 > 180 (20)	312 > 236 (15)	312 > 92 (23)
Fenamiphos	303 > 154 (15)	303 > 228 (10)	304 > 217 (21)	304 > 202 (34)
Fenbuconazol	198 > 102 (25)	198 > 129 (15)	337 > 125 (29)	337 > 70 (25)
Fenothiocarb	160 > 72 (10)	160 > 106 (10)	254 > 160 (8)	254 > 72 (10)
Fenpropimorph	128 > 70 (10)	303 > 128 (10)	304 > 147 (29)	304 > 119 (30)
Flusilazole	233 > 152 (15)	315 > 233 (10)	316 > 247 (16)	316 > 165 (28)
Hexaconazole	214 > 152 (20)	214 > 159 (20)	314 > 70 (10)	314 > 159 (25)
Hexazinone	171 > 71 (15)	171 > 85 (15)	253 > 171 (16)	253 > 71 (25)
Imazalil	215 > 41 (20)	215 > 173 (10)	297 > 159 (23)	297 > 255 (12)
Isoprocarb	136 > 103 (25)	136 > 121 (10)	194 > 95 (10)	194 > 77 (25)
Myclobutanil	179 > 125 (15)	179 > 152 (10)	289 > 70 (10)	289 > 125 (25)
Napropamide	128 > 72 (5)	271 > 128 (10)	272 > 171 (19)	272 > 129 (18)
Pendimethalin	252 > 160 (10)	252 > 191 (10)	282 > 212 (5)	282 > 194 (15)
Pyriproxifen	136 > 41 (10)	136 > 96 (12)	322 > 185 (25)	322 > 134 (25)
Tebuconazole	250 > 125 (10)	250 > 163 (10)	308 > 125 (33)	308 > 70 (38)
Thiabendazole	201 > 130 (25)	201 > 174 (15)	202 > 175 (23)	202 > 131 (32)
Thiamethoxam	247 > 139 (15)	247 > 182 (10)	292 > 181 (15)	292 > 211 (15)
Tricyclazole	189 > 135 (20)	189 > 162 (10)	190 > 163 (20)	190 > 136 (27)
Triflumizole	206 > 179 (15)	278 > 73 (10)	346 > 43 (15)	346 > 73 (10)

Table 1: MRM transitions of 30 pesticides by GC-MS/MS and LC-MS/MS systems.

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corporated into GC-MS and LC-MS, there is a dramatic increase in signal to noise ratio, greater specificity, and better quantitative performance. Hardware advances in both GC-MS/MS and LC-MS/MS have refined the performance of triple quadrupole MS for pesticide detection to ensure high performance is maintained throughout high throughput analysis. In GC-MS/MS, an axial ion source reduces the contact of ions with hot surfaces and avoids the matrix build-up on the ion source. Higher signal to noise ratio is maintained, reducing the need for instrument cleaning and the resulting downtime, while ensuring high performance is maintained, crucial for a high-throughput laboratory.

VIP-HESI technology ensures high signal-to-noise ratios, superior robustness, and broadens the analysis range of liquid chromatography techniques.

Design advances in LC-MS/MS also deliver similar improvements in robustness and sensitivity by optimizing ion transfer. The systematic loss of sensitivity resulting from residue deposition is overcome by use of an open orifice rather than a capillary interface between the liquid chromatography and mass spectrometry elements. An Active Exhaust further reduces chemical noise and increases sensitivity and specificity of trace analyte detection by reducing gas recirculation within the ion source.

A further point of development has been extending LC-MS/MS to cover thermally labile pesticide species that commonly breakdown during liquid chromatography eluent "over-heating" prior to nebulization. This is achieved by the incorporation of a vacuum insulated probe within the ionization unit and around the liquid chromatography eluent to reduce heat transfer to the sample. Vacuum Insulated Probe Heated Electrospray (VIP-HESI) technology ensures high signal-to-noise ratios, superior robustness, and broadens the analysis range of liquid chromatography techniques.

Advantages of CBS

Developing a multiple reaction monitoring method can be a time consuming task as there can be hundreds of pesticides to identify in a single run. Traditionally a chromatographic run is divided into fixed segments and only the MRMs eluted in each segment are monitored. However, residues eluting near the joint of the two adjacent segments, MRMs must be set up in both segments to assure detection. The need for duplicated MRMs leads to slower duty cycles that must be carefully optimized to ensure sensitivity is not lost from short dwell times. Compound Based Scanning (CBS) streamlines method development for multi-residue analysis. Following a number of initial runs to locate the retention time window for each compound, the optimal scan time is automatically calculated by the software, which processes all the overlapped retention time windows. In this way, the duty cycle is optimized and fixed segments are no longer required, which is greatly advantageous in a high-throughput laboratory.

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The CBS workflow focuses on the compounds rather than the individual MRMs. The MRM transition for an analyte does not need to be known. Instead the software auto-fills this information from a compound library containing more than 2,500 MRM transitions covering more than 900 contaminants. Each compound library is then linked to retention time, primary and secondary MRM transitions and collision energy. Using this library, CBS dramatically reduces the time taken to set the initial MRM methods to give accurate data while simultaneously improving workflow productivity.

The below case study explores how LC-MS/MS and GC-MS/MS systems incorporate these hardware and software developments to provide robust, fast, and simple analysis of complex food matrices.

Rapid Pesticide Analysis using LC-MS/MS and GC-MS/MS

Three vegetable matrix samples of rice, avocado, and spinach, representing low moisture content, fatty content, and high moisture content vegetable groups respectively, were extracted using the modified QuEChERS protocol developed at the U.S. FDA Lab at Irvine, shown in Figure 1 on page 33.

Thirty pesticides amenable for both GC-MS and LC-MS were spiked into three extracted vegetable matrices. Calibration solutions were diluted using extracted blank matrices and prepared for analysis using the EVOQ LC-MS/MS and the SCION GC-MS/MS (Bruker). The MRM method development workflow was set up using Compound Based Scanning. The target pesticides (Table 1, page 34) were selected from the software's MRM library before being exported to the CBS method editor. The dwell time for each MRM is then automatically calculated based on its retention time window (timed MRM). A "built-in" processing method allows for easy updates of the retention times and method parameters and automatically updates qualitative and quantitative ion ratios based on the standards.

Excellent sensitivity was achieved for multi-residue pesticides in various vegetable matrices using both GC-MS/MS and LC-MS/MS systems. Examples of 1 and 5 parts per billion spiked samples in a spinach QuEChERS matrix analyzed by LC-MS/MS and GC-MS/MS are shown in Figures 2a and 2b on page 34. R-squared values show excellent linearity was achieved with each matrix.

In Conclusion

The monitoring of pesticides in fruits and vegetables is a key priority for international food safety. Many emerging export economies have substantially different regulations to their Western counterparts. This means stringent monitoring of pesticides is therefore essential to meet international regulatory requirements and ensure product safety. However in complex biological matrices, achieving the accuracy and robustness needed for these routine quality control methodologies can be complex and time consuming. Hardware and software developments in tandem mass spectrometry coupled chromatographic systems provide the sensitivity and selectivity needed for such routine operations, while reducing operator input and instrument down time, and simplifying method development. ■

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Importance of Certified Reference Materials

Availability of CRMs for food testing procedures would ensure consistent, reliable results and could be used to establish sensitivity, linearity, and specificity during the validation of microbiological quality control methods

BY **CARA N. WILDER, PHD**
AND **LIAM GORMLEY**

Foodborne illnesses pose a significant economic and public health burden associated with product recalls, epidemiological tracking, extensive healthcare expense, and countless numbers of hospitalizations and deaths. The global sourcing of raw materials and distribution of products combined with the differences in regulations of agrochemicals and medicines mean that the contamination of food can also impact international trade. For food producers in the U.S., the FDA Food Safety Modernization Act (FSMA) has made identifying and tracing foodborne adulterants in raw and processed food products throughout the manufacturing process a matter of public law. However, as many food products are complex systems, it can be challenging to identify biological, chemical, and environmental adulterants, as well as discriminate between those that are harmful from those that are not harmful. Thus, the use of highly characterized, homogenous, authenticated control materials, such as certified reference materials (CRMs), is imperative in food testing.

Food products and raw materials can become contaminated during any stage in the process of food production to consumption, or "farm to fork." These contaminants can be biological, chemical, or environmental in nature, encompassing microorganisms, radiological hazards, natural toxins, drug residues, pesticides, harmful chemical reagents, allergens, parasites, and adulterants originating from soil, water, industry, and animals. When consumed, these contaminants may result in gastrointestinal symptoms such as abdominal cramping, nausea, vomiting, diarrhea, and dehydration. Depending on the causative agent of the foodborne illness, other neurological, gynecological, or immunological symptoms can present, which may lead to multi-organ failure, contributing to a high incidence of mortality.

In an effort to update U.S. food safety laws, FSMA was enacted in 2011, which provided a legislative mandate to require preventative control protocols and comprehensive reference materials to identify contaminants throughout the manufacturing process, as well as the authority to prevent intentional adulteration. The FDA now has oversight to ensure compliance with these aforementioned regulations, including mandated inspections, access to the records of food manufacturing facilities, requiring certain food testing to be carried out by accredited laboratories, and the ability to develop a program that enables laboratories to become accredited.

Emphasizing Accreditation

While several local, state, and federal government food testing laboratories have already pursued accreditation programs such as ISO/IEC 17025:2005, the accreditation of commercial laboratories is still in its formative years. While accreditation is not yet required, it is emphasized by FSMA as it offers a means to support the generation

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of reliable and traceable data that is consistent among food testing laboratories. Similarly, a recent guidance document released by the USDA Food Safety and Inspection Service (FSIS), entitled *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*, suggested that accreditation under ISO/IEC 17025:2005 helps to increase confidence in the accuracy of test results produced by a laboratory. Largely, accreditation ensures that all laboratory results are achieved through the proper obtainment and preparation of samples, the employment of scientifically sound testing methods and reference standards, and ethically-responsible, competent laboratory personnel. In turn, this provides additional confidence that a minimum standard of quality has been met throughout the food testing process.

Laboratories that are ISO/IEC 17025:2005 accredited require the use of CRMs when using reference standards for traceability; Section 5.6.3.2 of this guideline states, "reference materials shall, where possible, be traceable to the international system of units of measurement, or to certified reference materials." Essentially, these materials are biological or chemical measurement standards that are homogenous and stable with respect to one or more specified property and for which traceability and values of uncertainty at a stated level of confidence are established, where applicable. CRMs are produced under an ISO Guide 34:2009 accredited process to offer confirmed identity, well-defined characteristics, and established chain of custody, making them highly effective as standards in research and development as well as laboratory testing. Moreover, they are accompanied by a certificate that provides the value of the specified property, the expiration date, and the proper use, thus confirming that the necessary procedures have been carried out to ensure both validity and traceability.

CRM Practicality

Presently, a number of CRMs have been developed for use by ISO/IEC 17025:2005 accredited food testing laboratories for the analysis of quality assurance and product safety. For quality assurance, CRMs are frequently used for method validations, such as the calibration of laboratory equipment or the examination of new identification, detection, or cleaning methods. This form of testing is needed to assess the quality of the measurement results as well as to demonstrate their traceability to a stated reference. CRMs are also used to evaluate the performance of laboratories and laboratory personnel through proficiency testing. The primary aim of this latter form of testing is to enable laboratories to monitor their performance for the detection and quantification of a given analyte or contaminant, and compare it with that of their peers. Moreover, it provides information to participants on any technical issues and methodologies relating to the testing of food products. Essentially, the use of CRMs in quality assurance testing helps to ensure that the data generated by a particular food testing laboratory is consistent, high quality, reliable, and traceable.

In addition to their importance in the quality assurance of food testing personnel and procedures, CRMs are essential for the internal quality control of routine food analyses. Because the performance of food testing methods can vary between laboratories due to technical and human factors, variations in the recovery of microbial contaminants or specific analytes, or the

unpredictable nature of microorganisms, the use of homogenous internal controls, such as CRMs, can be employed to help demonstrate the credibility of analytical results and the comparability of results from different laboratories. This is particularly true for standard procedures designed for the microbiological analysis of food products; often, these procedures are designed for one specific strain and may not be applicable toward the detection or quantification of other microbial species.

Currently, biological and chemical CRMs are available from both official and commercial manufacturers that are ISO Guide 34:2009 accredited, such as ATCC and LGC Standards. For CRMs specifically used in food testing, preparations can be obtained as either an inoculated (where applicable) and standardized preparation of a specific food material, or as a preserved and defined preparation that can be used to inoculate or fortify various food preparations. This latter format, in particular, is useful in that it allows the user to inoculate a known quantity of the defined CRM into an appropriate food matrix that resembles the routine samples as much as possible. This format allows for testing the influence of matrix constituents, which can significantly affect the accuracy of measurements in microbial, biochemical, and chemical analysis of food. For microbiological CRMs, this format also allows for testing competitive microbial strains as well as the development and validation of growth media and species specific test methods.

Overall, the contamination of food poses a significant health burden on the human population that is largely preventable and frequently under-reported. By urging food testing laboratories to gain accreditation, and consequently, employ the use of CRMs for quality assurance and as internal controls in food testing procedures, we can be confident that the results generated from food testing analyses are high quality and reliable. In turn, this will help strengthen the food safety system by contributing to the prevention of foodborne outbreaks and the integrity and quality of food. ■

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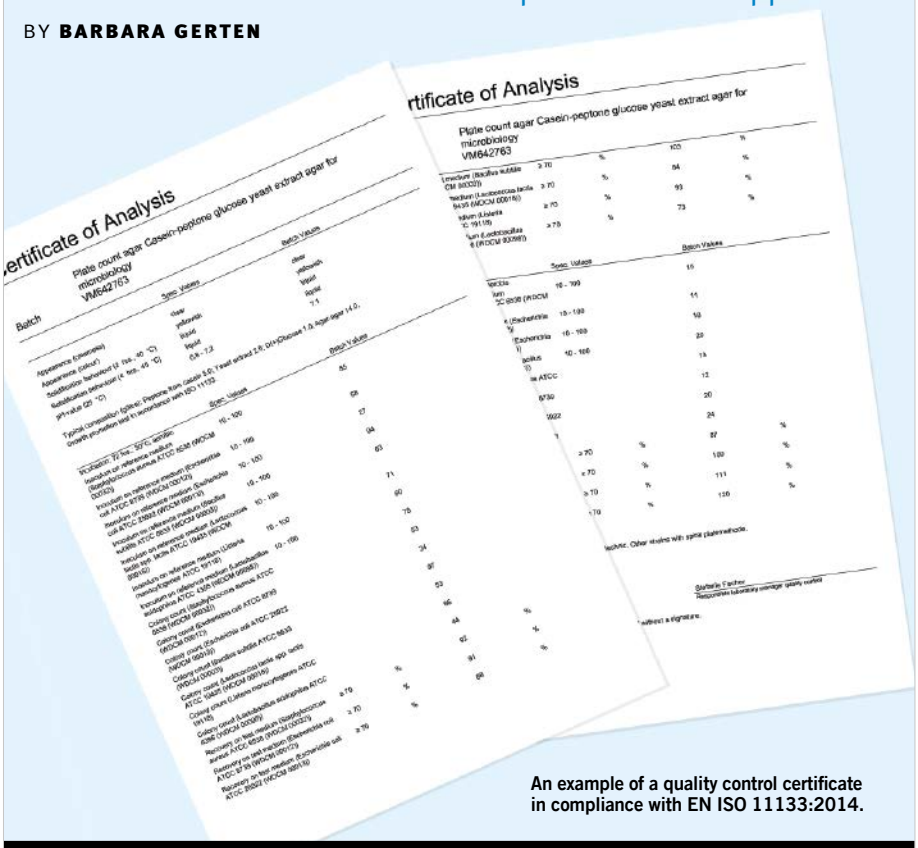
Lab Implementation of ISO 11133:2014

New mandatory standard for the preparation and quality control of culture media will reduce the workload for the qualification of new culture media batches procured from suppliers

BY **BARBARA GERTEN**



An example of a quality control certificate in compliance with EN ISO 11133:2014.

In March 2014, the International Organization for Standardization (ISO) introduced the revised EN ISO 11133:2014, which is now a mandatory standard for all accredited laboratories that perform microbiological testing of food, animal feed, or water using culture media. The standard was compiled by a joint ISO working group from food and water standardization and titled "Microbiology of food, animal feed and water—preparation, production, storage, and performance testing of culture media." EN ISO 11133:2014 defines the preparation and quality control of culture media, the requirements of which are applicable to all categories of culture media prepared for use in laboratories performing microbiological analyses. This new standard replaces EN ISO TS 11133-1:2009 (Preparation of culture media), EN ISO TS 11133-2:2003 (Performance testing of culture media, both for food and feed microbiology), and ISO 9998:1991 (Requirements for microbiological media for water testing).

EN ISO 11133:2014 applies to any commercial or non-commercial entity that is producing and/or distributing culture media intended for the microbiological analysis of food for human consumption, animal feed, and samples from the manufacturing environment of such products, as well as water for consumption or use in food production. The new standard includes all types of culture media, ranging from dehydrated to ready-to-use media for classical to alternative microbiological testing methods.

All European Union (EU) countries are adopting EN ISO 11133:2014 and the standard is currently published in French and German. In addition, all accreditation bodies worldwide recognize EN ISO 11133:2014 because it is now a full EN ISO standard.

An EN ISO 11133:2014 Overview

EN ISO 11133:2014 covers requirements for the preparation, production, storage, and performance testing of culture media. Under the new standard, all conditions for performance testing should resemble the intended sample testing conditions as closely as possible in order to provide the most accurate and meaningful results. For example, culture media for quantitative testing must now be tested quantitatively, and media used in conjunction with membrane filters must now be tested in combination with these membrane filters. The requirements for performance testing are specified in detail, which includes step-by-step instructions and flowcharts for performing and evaluating performance tests.

The standard provides comprehensive specification tables for most culture media for both food and water microbiology. These tables include the medium's target microorganism; relevant ISO standard; each medium's function to be tested (productivity, selectivity, specificity); the appropriate control strains for each medium's function, including their World Data Centre for Microorganisms numbers, and; test criteria and/or characteristic reactions and other practical information (Table 1, page 42).

EN ISO 11133:2014 contains detailed instructions for the maintenance of microbial strains and the preparation and standardization of working cultures and inoculation suspensions. It specifies the optimal number of colony forming units, or CFU, per plate or membrane filter and describes how productivity ratios and limits are to be determined.

Quality Assurance Responsibilities

Many laboratories source their culture media from suppliers both to streamline their workflows and to ensure high quality and batch-to-batch consistency. EN

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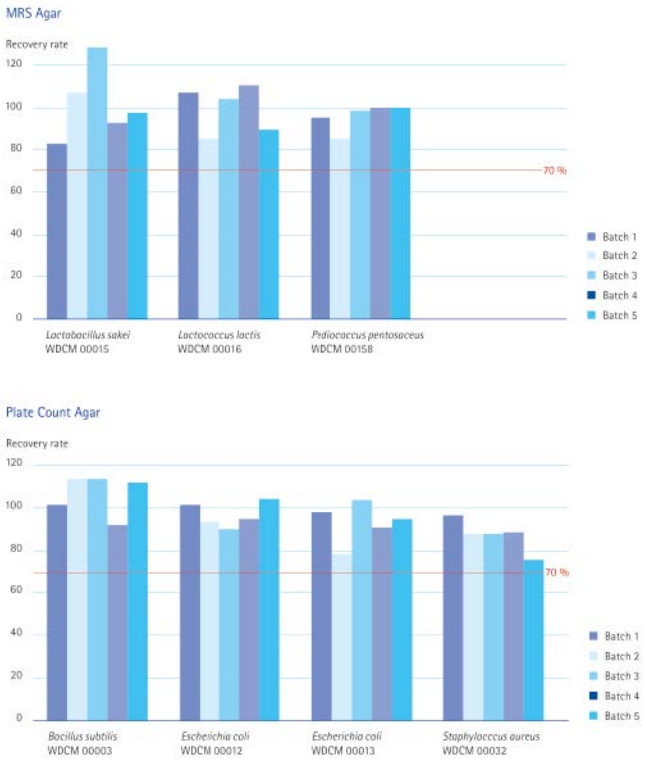

Figure 1: Quantitative productivity testing results of selective (MRS) and non-selective (PCA) solid agar media for enumeration. The results show that the five batch samples of each culture media achieved the required performance for all test microorganisms. As the reference medium for MRS, a previously validated batch of MRS was used, and TSA was used for PCA as specified in EN ISO 11133:2014.

ISO 11133:2014 takes into account the ever-increasing number of laboratories sourcing their culture media from suppliers by stipulating quality assurance requirements not only for laboratories that continue to prepare their media in-house, but also for manufacturers of culture media. With a clear line drawn between the responsibilities of users and suppliers, laboratory managers can now reliably evaluate which duties and responsibilities will transfer to the manufacturer when they make the decision to procure culture media from a supplier.

Many laboratories source their culture media from suppliers both to streamline their workflows and to ensure high quality and batch-to-batch consistency.

For laboratories that continue to produce their culture media in-house, each batch can sufficiently be tested using a single test strain named in the standard. Manufacturers, on the other hand, must test each batch using several microorganisms. Laboratories can rely upon the performance tests that the manufacturer conducts for ready-to-use media only as long as the transport conditions are observed and the manufacturer's QC test is performed according to the requirements of the standard. It is the end users responsibility to ensure that batch testing was performed according the requirements of EN ISO 11133:2014 by procuring the quality control certificate as a supporting document from the manufacturer. This certificate should disclose the test organisms used, the acceptance criteria of the performance tests, and the test results.

Performance Testing

Suppliers must conduct rigorous qualitative and/or quantitative testing on all ISO 11133:2014 compliant culture media that they provide to laboratories. Below are a few examples of testing criteria for liquid and solid selective and non-selective culture media.

Liquid Culture Media. Buffered Peptone Water (BPW) is used for the non-selective pre-enrichment of *Salmonella* bacteria in food. The EN ISO 11133:2014 testing criterion for BPW is turbidity, which must either be weak or good.

Fraser broth is used for the selective enrichment of *Listeria monocytogenes* in food. The EN ISO 11133:2014 testing criterion for Fraser broth is the growth of more than 10 colonies on *Listeria* selective agar according to Ottaviani and Agosti. When inoculated as a mixed culture with *Escherichia coli* and *Enterococcus faecalis*, only *L. monocytogenes* should be able to grow on this agar as characteristic blue-green colonies with opaque halos.

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Selective media for enumeration of microorganisms

Media[a]	Type[e]	Microorganisms	International Standard	Function	Incubation	Control strains	WDCM numbers[c]	Reference media	Method of control	Criteria	Characteristic reaction
Agar Listeria according to Ottovani and Agosti	S	*Listeria monocytogenes*	ISO 11290-2	Productivity	(44±4)h/ (37±1)°C	*Listeria monocytogenes* 4b *Listeria monocytogenes* 1/2a	00021[b] 00109	TSA	Quantitative	$P_R \geq 0.5$	Blue green colonies with opaque halo
				Selectivity		*Escherichia coli*[d] *Enterococcus faecalis*[d]	00012 or 00013 00009 or 00087	–	Qualitative	Total inhibition (0)	–
				Specificity		*Listeria innocua*	00009 or 00087	–	Qualitative	–	Blue green colonies without opaque halo

Selective enrichment media

Media[a]	Type[e]	Microorganisms	International Standard	Function	Incubation	Control strains	WDCM numbers[c]	Reference media	Method of control	Criteria	Characteristic reaction of target microorganism
Fraser	L	*Listeria monocytogenes*	ISO 11290-1	Productivity	(48±2)h/ (37±1)°C	*Listeria monocytogenes* 4b +*Escherichia coli*[d] +*Enterococcus faecalis*[d]	00021[b] 00012 or 00013 00009 or 00087	–	Qualitative	>10 colonies on Agar Listeria according to Ottaviani and Agosti	Blue green colonies with opaque halo
						Listeria monocytogenes 1/2a +*Escherichia coli*[d] +*Enterococcus faecalis*[d]	00109 00012 or 00013 00009 or 00087				
				Selectivity		*Escherichia coli*[d]	00012 or 00013	–	Qualitative	Total inhibition (0) on TSA	–
						Enterococcus faecalis[d]	00009 or 00087	–	Qualitative	<100 colonies on TSA	–

a Full names of media abbreviated terms are given in Table E.2.
b Strains to be used as a minimum.
d Strain free choise; one of the strains has to be used as a minimum.
e L: liquid medium, S: solid medium, SS: semi-solid medium.

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Table 1: Two extracts from Table E.1 in the annex E of EN ISO 11133:2014. (Modified from ISO 11133:2014.)

(Continued from p. 41)

Table 2 at right shows the results of qualitative tests performed for five batches of Fraser broth (EMD Millipore). The *E. coli* and *E. faecalis* strains are included in the testing criterion to prove the selective properties of the medium.

Solid Agar Media. Two common solid agar media from EMD Millipore are selective de Man, Rogosa, Sharpe (MRS) agar for enumeration of lactic acid, and non-selective Plate Count Agar (PCA) for colony count. The EN ISO 11133:2014 quantitative productivity testing criterion for each of these solid media agar is recovery rates of 70 percent or more for every test organism. Figure 1 on page 41 shows the results of quantitative tests performed for five batches of MRS and PCA medium.

Conclusions

EN ISO 11133:2014 is a mandatory standard for all accredited laboratories that perform microbiological testing of food, animal feed, or water using culture media. The goal of this new standard is to improve consumer safety with respect to food and beverage products, and the guiding principle is that performance testing conditions should mimic the intended sample testing conditions as closely as possible.

Under the new standard, laboratories that source their culture media from a supplier can ensure that the media is manufactured and certified according to the latest international standard, EN ISO 11133:2014, by procuring the quality control certificate as a supporting document. Ultimately, this standard should reduce the workload for the qualification of new culture media batches procured from suppliers. In the supporting document, suppliers should provide quantitative information about the growth of both "wanted" microorganisms (bacteria that should grow on a specific medium) and "unwanted" microorganisms (bacteria that should not grow on a specific medium). The highest quality media will support only the growth of "wanted" microorganisms. ■

Test organisms	Batches 1 to 5	
Listeria monocytogenes WDCM 00021 + *Escherichia coli* WDCM 00012 + *Enterococcus faecalis* WDCM 00009	> 10 colonies on Agar Listeria according to Ottaviani and Agosti	Blue-green colonies with opaque halo
Listeria monocytogenes WDCM 00109 + *Escherichia coli* WDCM 00013 + *Enterococcus faecalis* WDCM 00087	> 10 colonies on Agar Listeria according to Ottaviani and Agosti	Blue-green colonies with opaque halo

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Table 2: Qualitative productivity testing results of the selective enrichment medium Fraser broth.

Gerten, an application training scientist at EMD Millipore, is a member of the ISO committee for microbiological standards regarding food and water testing, and was involved in the revision of EN ISO 11133. Reach her at barbara.gerten@merckgroup.com.

Automation Manages Robust HACCP (and HARPC!) Programs

How automation helps define all HACCP plan parameters, manages CCPs and workflow, and sees process through to pre-shipment programs and reporting

BY **BARBARA LEVIN** AND **DAN BERNKOPF**

A HACCP (Hazard Analysis Critical Control Points) Plan is the foundation for most food safety programs. It provides for the food safety requirements that accomplish a science-based risk assessment, and risk control management system, for inbound suppliers through internal manufacturing processes and ultimately to pre-shipment review and sending finished products out the door and into commerce—upstream, downstream, and internally. In other words, they set a company's food safety standards "for what comes in, what you do with it, and what goes out." The same will hold true for HARPC (Hazard Analysis and Risk-Based Preventive Controls) plans under FDA's Food Safety Modernization Act (FSMA).

But managing robust HACCP/HARPC plans presents many challenges, including monitoring multiple, complex plans across a company's facilities/operations; verifying workflow and completion of all tasks associated with Standard Operating Procedures (SOPs), Prerequisite Programs (PRPs) and Critical Control Points (CCPs); validating that the plan elements are working; getting timely non-conformance information for Corrective/Preventive Actions (CAPA); ensuring all requirements are met prior to sending product into commerce; analyzing data across the entire operation, which is typically in paper form, for continuous improvement; and accessing accurate data and records for HACCP/HARPC audits.

This is why more and more food and beverage companies are deploying software solutions for HACCP/HARPC automation. This wasn't always the case. In the past, food safety technology adoption was difficult because safety and quality assurance folks for the most part aren't sitting at their desks in front of computers—and enterprise systems were often too expensive for the food industry's slim profit margins.

But today, highly secure, cloud-based HACCP/HARPC automation technologies make this type of automation both possible and practical. Cloud solutions require no capital hardware/software investments and can be accessed anywhere, at any time, from mobile devices. This makes them both affordable and effective to provide key benefits for HACCP/HARPC management, including the ability to automate food safety plans for every product group and facility; access all of

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your organization's safety data from a single, central repository for trending; respond "on demand" to USDA, FDA, and customer inquiries and audits; and get real-time, non-compliance alerts for timely CAPAs.

How Does HACCP/HARPC Automation Work?

There are a variety of HACCP/HARPC automation solutions on the market and you will have to evaluate which of the options best meet your needs, but in general, some of the capabilities you should look for in these applications include functionality that allows you to do the following.

- Define, manage, and maintain HACCP/HARPC program and document requirements and records—for CCPs, PRPs, SOPs, and more—for multiple plans and facilities.
- Automate workflow and task scheduling—including CCP monitoring activities; send auto-notifications when tasks are due; and issue escalating alerts if tasks aren't completed on time.
- Define specifications, and then capture safety data—from suppliers, equipment, direct observation, and internal/external labs—electronically and in real time.
- Automatically analyze captured data, against specifications and requirements, and issue non-conformance alerts in real time.
- Generate, resolve, and document CAPAs before a food safety issue gets "out of control."
- Access all food safety and quality assurance (FSQA) data and records from a single, centralized repository for reporting, benchmarking, trending, and continuous improvement.
- Have on-demand access to the records and documentation you need to respond promptly to USDA, FDA, and customer inquiries and audits.

Key Benefits of HACCP/HARPC Automation

Get Out From Under "Mountains" of Paper. HACCP plans place a heavy burden on FSQA departments trying to comply using manual processes and records—and it is expected that HARPC plans will do the same. Automation can help you get out from under all of this paper with functionality that manages, verifies, and maintains programs and associated data and records. HACCP/HARPC automaton allows for the following abilities.

- Easily access and revise plans and flowcharts for annual and/or mandated reassessments, new regulatory requirements, and new or revised processes.
- If you have task scheduling features, all of your CCPs, PRPs, and other tasks can be defined and scheduled for due dates/times/frequency. Non-completion notifications, which can typically be sent via text and email to identified stakeholders, can ensure that tasks get completed on time and help avoid rework and shipment delays.

> Automatic COA generation...allows product to move faster to the next point in your value chain—meaning that shipment to customers can be expedited.

- Automatically generate unalterable time/date stamps on all records—including non-conformance alerts and CAPA documents—to ensure greater efficacy of records. Some automation solutions also support electronic signatures and 21 CFR Part 11 compliance.
- Facilitate faster shipment of product to customers—including Certificate of Analysis (COA) generation or positive release documentation—when no non-conformances are detected. If using a cloud-based system with roles-based security, you might even allow customers "visibility and transparency" by allowing them to access the FSQA documentation and records for the products they receive.

Make Sure HACCP/HARPC Programs are Being Followed to a "T." One of the biggest challenges to managing a successful HACCP/HARPC plan is to ensure that you are "saying what you do, doing what you say, making sure it works, and making sure it's documented." Are all facilities and suppliers following your most current plan(s)? Using the most up-to-date forms? Ensuring proper records for pre-shipment reviews? HACCP/HARPC automation addresses these challenges in the following ways.

- Some automated systems will provide pre-built form configuration templates that allow you to easily set up your HACCP/HARPC program requirements and ensure that only the most up-to-date plans and forms are used.
- Workflow verification can be auto-generated, including pre-shipment review authorizations and positive releases, with e-signatures. Depending on the size and complexity of operation, you may choose to integrate your HACCP/HARPC solution with Enterprise Resource Planning or Materials Resource Planning systems—signaling product acceptance and release.
- Most HACCP/HARPC systems have a variety of real-time dashboards that can display trends for compliance status of sanitation and environmental controls, pest control, preventive maintenance, test/task data results, CAPAs, and other program components. If the solution you implement has a mobile application, you can monitor the program from anywhere there is an Internet connection via a laptop, tablet, or smartphone.
- Automation allows new and updated requirements to be "cascaded" throughout your food supply chain so compliance is immediately enforced by ensuring that only current plans and forms are used by suppliers, in your plants, and for documents sent to customers prior to shipment.

Respond to Audits and Inquiries in a Matter of Minutes vs. Hours or Days. Responding to HACCP/HARPC program questions—during a USDA inspection, FDA inquiry, or perhaps a customer audit—is time-consuming and disruptive to operations. Additionally, if records can't

be located or verified, regulatory audit expansion is very likely to occur and business relationships can be damaged. HACCP/HARPC automation can help you be ready 24/7/365 for such audits and inquiries by allowing you to perform the following functions.

- Search a central repository of the relevant program data—in most solutions both current and historical—for fast, accurate response.
- Auto-organize all relevant documents for each type of audit by product, facility, incident, or any other parameter required by HACCP/HARPC plan(s).
- Bring a new level of efficacy to FDA and USDA program compliance with unalterable time/date stamps offered by some HACCP/HARPC automation solutions.

Building a Business Case for Buy-In

This all sounds pretty good, right? But given low food industry profit margins, it's often necessary to be able to build an ROI-based business case for technology investments. If we think about the other types of automation solutions that many food companies have in place—such as human resources or financial applications—they were approved because they save time, save money, and create efficiencies to provide ROI. This same holds true for FSQA technology, including HACCP/HARPC systems. These solutions also save time and money and create operational efficiencies that streamline and improve program management. Examples of ways in which HACCP/HARPC automation can create ROI include the following.

- Reduction of manual labor: automated task monitoring and population of direct observation forms via mobile devices, or direct data entry into the system, not only increases accuracy—these capabilities also result in time/labor savings due to a reduction in manual processes and related errors.
- Faster product throughput: automatic COA generation, when no non-conformances are detected, allows product to move faster to the next point in your value chain—meaning that shipment to customers can be expedited.
- Reduction in the cost of non-conformance: real-time data analysis and timely CAPAs help manage product risks, minimizes product rework, and expedites product release times.

In Summary

HACCP plan management does not have to be a time-consuming, error-prone practice that lends itself to food safety professionals spending more time entering data versus analyzing it to find areas for FSQA improvement. By leveraging HACCP/HARPC automation innovations, food and beverage companies can manage robust and complex plans, maximize compliance, minimize non-conformances, promote audit readiness, and create ROI. ■

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Bridging Industry and Regulatory to Enhance Safety

The cross-functional collaboration of educational programs will enable managers to properly respond to an illness outbreak or recall | BY **RANCE BAKER** AND **ELIZABETH LANDEEN**

If you're in the food service industry you know that few industries are as complex or evolve as rapidly as this one. The ever growing list of responsibilities for a successful food manager suggests someone who is part chef, fortune teller, engineer, magician, recruiter, and trainer who is able to:

- Forecast changing consumer preferences and trends,
- Identify global sourcing to meet the demands of fickle customers,
- Ensure training among all staff despite high employee turnover, and
- Diligently implement safe food handling practices to prevent a food incident.

These are just some of the challenges food industry professionals face. Few challenges, however, are as critical or as daunting as preventing illness, and possibly worse, as a result of a foodborne illness outbreak. It is not surprising that industry professionals, who were eager to ensure they would be prepared to handle an outbreak or a food recall, were the impetus for a program most recently funded by the FDA called the Industry-Foodborne Illness Investigation Training and Recall Response (I-FIIT-RR).

Many organizations are involved in efforts to mitigate the effects of the estimated 48 million annual foodborne illnesses on public health. The National Environmental Health Association (NEHA) developed a program that brought various *regulatory* professionals together to collaborate on foodborne investigation trainings that they were often called upon to assist. These workshops, called Epi-Ready, brought together for the first time laboratory, public health, environmental health, and epidemiology practitioners to train for an outbreak investigation and look at the roles, responsibilities, and perspectives of each profession to form a better collaboration and response.

News about the Epi-Ready workshops spread among food industry professionals who could see the immense benefit of receiving training *prior* to an outbreak alongside the regulatory people who would be involved in an outbreak investigation. The collaborative training model of I-FIIT-RR is directed at the retail food industry, which provides a direct link to the consumer and food products. This completes the communication loop between environmental health professionals who are tracking the potential cause of an illness outbreak or food recall and the public whom they strive to protect.

"Finally industry is brought into the fold as active participants in the investigations process," says Cindy Rice, RS, MSPH, CP-FS of Eastern Food Safety." They have the ability to respond, and this course brings them out of the dark, giving them what they need to know so they can take action." Rice is a national food safety consultant who owned her own catering, café, and food manufacturing businesses.

Working Together

The success of the four I-FIIT-RR workshops held in 2013 and 2014 was immediately apparent. Regulators, who had plenty of knowledge about illness investigations but limited time and staffing resources to go it alone, complemented industry professionals, who were committed to being active participants in the investigations and recall process but needed support and guidance from their regulatory counterparts. As a direct result of the workshops, not only were collaborative relationships forged, but several resources were created and are now available from www.nehafoodsafety.org for food safety professionals that benefit both industry and regulatory agencies.

The Recall Response Form allows industry to document their activities during a food recall and can be used to streamline com-

munication between industry and the regulatory agency during a food recall. *Proactively* forwarding this form to the appropriate food regulatory agency allows that agency to be fully informed early on in the recall process, improves collaboration, and enables a more efficient process that maximizes use of limited resources.

Another resource was developed that sums up the collaborative ideas from industry and regulators to improve food recall investigations. Suggestions to Improve Recall Response is also available at www.nehafoodsafety.org.

NEHA now has a fully vetted and developed I-FIIT-RR training workshop on retail food industry outbreak investigations and recall response. The workshop is also consistent with and incorporates the nationally recognized and approved guidelines, *Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments* developed by the Council to Improve Foodborne Outbreak Response. I-FIIT-RR trainings continue to empower food establishments across the U.S. NEHA is also in the process of developing an online version of this training, which will be available for industry and any other interested parties. In addition to these workshops, NEHA will be offering several live webinars on food recalls and effective industry response in 2015.

A Thirst for Knowledge

With roots well-grounded in food safety, NEHA began in 1937 as a way for the then developing profession of environmental health to establish standards of practice that prove an individual has mastered a body of knowledge and acquired practical experience to perform work responsibilities to protect public health. The Registered Environmental Health Specialist/Registered Sanitarian (REHS/RS) credential proves demonstrated expertise in conducting facility and systems inspections, leading complaint and epidemiology investigations, promoting public health awareness, and responding to community emergencies. While food safety comprises a large percentage of an REHS/RS professional's time, they are also called upon to apply process and technical knowledge to areas of water quality, air quality, hazardous material handling, and vector control.

The evolution of the U.S. and global food industry, from supply to processing, distribution, and retail, created the need for more specialized, in-depth food safety training that focused exclusively on this unique and complex industry. Recognizing that retail food managers are the frontline staff playing a crucial role in ensuring food safety for consumers, NEHA developed the Certified Professional–Food Safety (CP-FS) credential. This credential can be obtained by someone who has a food background; it provides expertise in:

- Developing food safety policies, procedures, and training;
- Assessing food safety, hazard analysis and critical control points (HACCP) principles, food microbiology, etc.;
- Reviewing facility/building plans in compliance with local laws, regulations, and permits;
- Investigating foodborne illness;
- Performing recall activities;
- Managing food defense practices; and
- Responding to emergencies.

"The CP-FS challenged me to study and grow in a specific area, which has served me well," says Lars Johnson, CP-FS, president of LAJ Consulting, LLC/FoodSafetyGuy, who has 25 years of food service operations experience. "I find that having the CP-FS gives me an advantage over others, having to learn more about the underlying biology, regulatory perspective, and equipment standards. I also see benefit in having this credential because the biannual renewal and the CE requirement forces me to stay current and also to engage other environmental health professionals in relevant discussions."

The advent of the Food Safety Modernization Act (FSMA) adds to the arsenal of required knowledge for those involved in any aspect of the food supply chain. The Global Food Safety Initiative aims to assure the safety of the food supply chain through collaboration between the world's leading food safety experts from retail, manufacturing, and food service companies, as well as others. NEHA's involvement with policy and these types of collaborations in the food industry occurs on many levels and ensures that the food safety credentials it offers serves professionals who work in a variety of settings, is relevant to their jobs, and remains current to keep pace with frequent changes in the industry.

More Educational Options

Two additional food safety credentials—Certified in Comprehensive Food Safety (CCFS), which prepares those managing and evaluating food facilities and food production processes across the entire food chain supply, and the Food Safety Auditor, which is still in development—provide advanced levels of training to meet the goals of food safety professionals. The CCFS is geared toward a more seasoned professional who upon successful completion of the credential is trained to manage the food flow; evaluate food facilities and equipment; ensure regulatory compliance; prevent contamination and adulteration; and manage a food defense plan, adverse events, and a sample collection program.

There is no shortage of programs that offer training in food safety. When choosing where or how to obtain food safety training, managers have many factors to consider including reputation of the organization, cost, relevance to meet the level of the trainee, availability of updates and revisions, and access to a variety of training formats. In addition, food safety professionals must understand local, state, national, and global regulations that affect their facility operations. The benefit of obtaining a nationally recognized credential is the transferability across state lines, and the requirement for continuing education to maintain the credential ensures that the professional is up-to-date on the most recent changes affecting the industry.

Collaborating with industry and all levels of government provides a bridge between regulators and food professionals in retail, manufacturing, and processing—an opportunity to work together towards the same goal. With the support of their food regulatory agencies, industry representatives can take coordinated steps to respond properly to an illness outbreak or food recall. Swift, appropriate action can help to minimize unsafe products ignored or left behind on the shelves of stores, in restaurants, and in homes and restores faith in the food service industry. Individuals and organizations with demonstrated success in facilitating cross-functional collaborations and with specialized expertise in the food supply chain will be a crucial factor in creating an efficient worldwide system that promotes best practices for a safe global food supply. ■

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Market Expanding for Diagnostic Testing

BY **KATHY HOLLIMAN**

THE FDA'S GROWING FOCUS ON PREVENTING FOOD-borne illness rather than just responding after an outbreak has occurred is prompting big demand and growth in the diagnostic testing market. Diagnostic testing kits are an essential part of this growing market as large food producers look for methods to monitor food pathogens while keeping their testing costs under control.

As part of the Food Safety and Modernization Act (FSMA), the FDA will hold food companies accountable for preventing contamination, with the requirement for comprehensive, science-based preventive controls across the food supply. Food facilities must implement a written preventive controls plan that includes a monitoring program to minimize or prevent hazards that can affect food safety.

According to Tim Lawruk of Romer Labs in Newark, Del., his company has experienced increased interest in food pathogen tests in anticipation of FSMA implementation. "This is particularly true as producers shift their emphasis to environmental monitoring for pathogens, as opposed to finished products testing, as a preventative measure to detect pathogen issues in their facilities," he says.

Additionally, smaller food producers are investing in food allergen test kits as they try to make their facilities HACCP compliant, Lawruk says.

Food producers can be expected to seek innovative products that improve the efficiency of testing for food pathogens, Lawruk explains. Many pathogens, such as *Listeria*, are very slow growers so this requires innovative enrichment media and sensitive detection methods. "The next big improvement in pathogen testing will be test results in a single work shift so that decisions can be made the same day, with less product held in storage, and associated costs reduced." ■

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Dual Energy X-ray

Ishida IX-G2 X-ray inspection system uses a dual energy process that compares absorption of X-rays on two levels. The technology improves detection of low-density objects in overlapped products. Unit is adept at detecting thin pieces of metal, glass, rubber, hard bones, and other foreign objects in products that have uneven surfaces, like cereal and certain frozen foods. The IX-G2 also includes functions for weight verification and detection of missing items, incomplete filling, product defects, incorrect alignment, or products trapped in package seals. **Heat and Control, 800-227-5980, www.heatandcontrol.com.**

Enterprise Quality Hub

InfinityQS ProFicient 5.2 is a manufacturing Intelligence platform powered by centralized SPC analytical software engine. This version has more options for creating and customizing reports in the cloud-based reporting feature. Manufacturers can incorporate acceptance sampling plans of their choosing into the platform and comply with the U.S. FDA and the ISO standards. ProFicient 5.2 Acceptance Sampling derives actionable intelligence from standard acceptance sampling data through in-depth comparative analyses from one lot, manufacturer, or supplier to another. **InfinityQS International, 800-772-7978, www.infinityqs.com.**

pH Electrode with Bluetooth

HALO is a professional pH probe with Bluetooth Smart technology. It is a double junction, refillable glass pH probe with a built-in temperature sensor that can be used virtually anywhere. Using Bluetooth Smart technology, HALO transmits measurement data directly to an iPad running the Hanna Lab App. The Hanna Lab App is a free application that turns the iPad into a full-featured pH meter when used with the Hanna HALO pH electrode. Functions include calibration, measurement, continuous data logging, graphing, and data sharing. Measurement and logging of pH and temperature at one-second intervals start as soon as the probe is connected. Measurements can be displayed with tabulated data or as a graph. **Hanna Instruments, 800-426-6287, www.hannainst.com.**

Footwear Sanitization

HACCP SmartStep Footwear Sanitizing System reduces cross-contamination from footwear before employees enter the production area or other critical control zones. This foot-operated unit uses compressed air to deliver a finely atomized mist of Alpet D2 Surface Sanitizer to the bottom of the employee's footwear. The mist provides ample coverage to footwear soles, yet uses only 0.2 ounces of chemical, which minimizes chemical waste and improves moisture control. Multiple units can be placed throughout the plant wherever pathogen reduction from footwear is needed, and with the optional handles and boot scrubber, the HACCP SmartStep System can be customized to meet users' needs. **Best Sanitizers, 888-225-3267, www.bestsanitizers.com.**

Tetracycline Detection

MaxSignal Tetracycline ELISA Kit for the detection of tetracycline residues in meat, honey, and other food samples features ready-to-use standards that do not need to be re-suspended or diluted—further simplifying tetracycline screening of multiple samples and increasing the reproducibility of the assay. Extraction protocols have eliminated the need for immunoaffinity columns during the sample preparation. The detection limit for honey is 3 ppb and 1.5 ppb for meat. **Bioo Scientific, 888-208-2246, www.biooscientific.com.**

In Other Product News

Romer Labs' AgraQuant Gluten G12 ELISA test is now an AOAC Official Method and approved by AACCI; and its AgraStrip Gluten G12 lateral flow test obtains AOAC-RI approval.

Invisible Sentinel's *Veriflow* assays are now being distributed in New Zealand by **New Zealand Medical and Scientific.**

Rite-Hite Holding's line of loading dock seal and shelter products previously branded as Frommelt products are now branded under the Rite-Hite name.

QIAGEN's *mericon* Pathogen Detection Assays for *Listeria* species and *Listeria monocytogenes* receives AOAC PTM certification from the AOAC-Research Institute.

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Events

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Internal Auditor Workshop
Twin Falls, Idaho
Visit www.techhelp.org
or call 208-364-6188.

27-29
International Production & Processing Expo
Atlanta, Ga.
Visit http://ippexpo.com.

MARCH

4-6
Global Food Safety Conference
Kuala Lumpur, Malaysia
Visit www.tcgffoodsafety.com.

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

APRIL

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

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

MAY

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

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

JUNE

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

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

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

JULY

11-14
IFT
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