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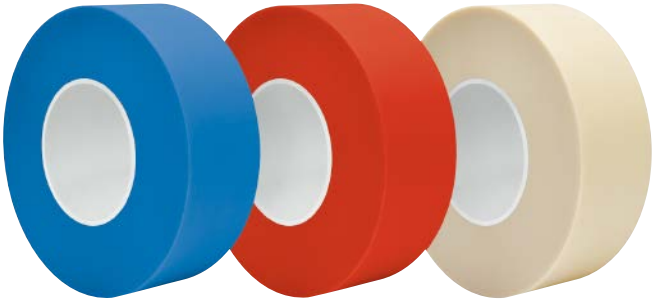

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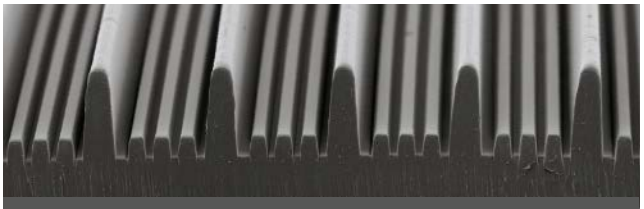

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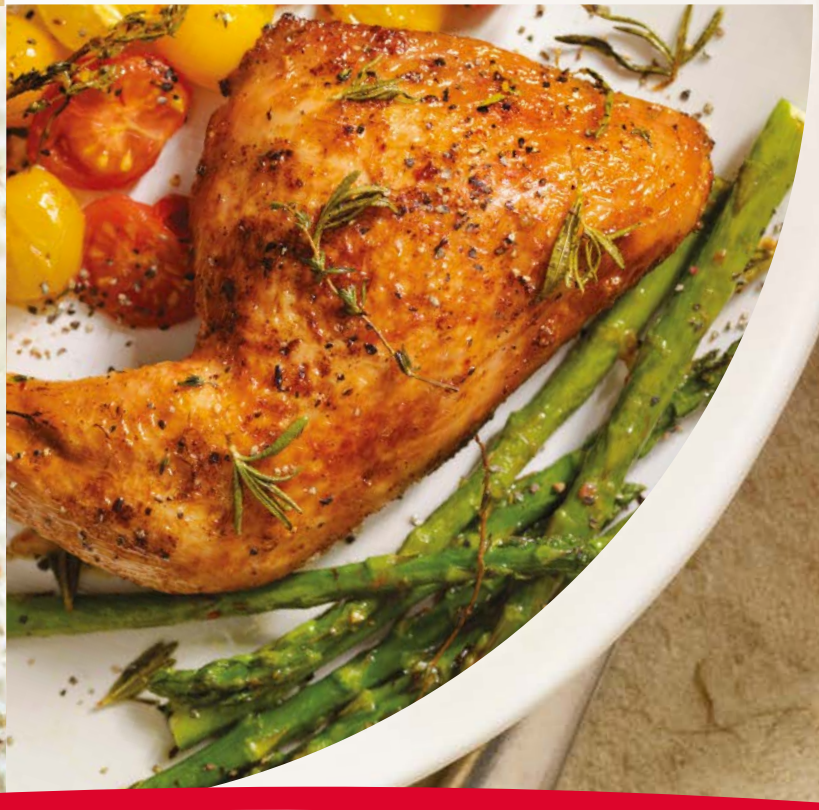

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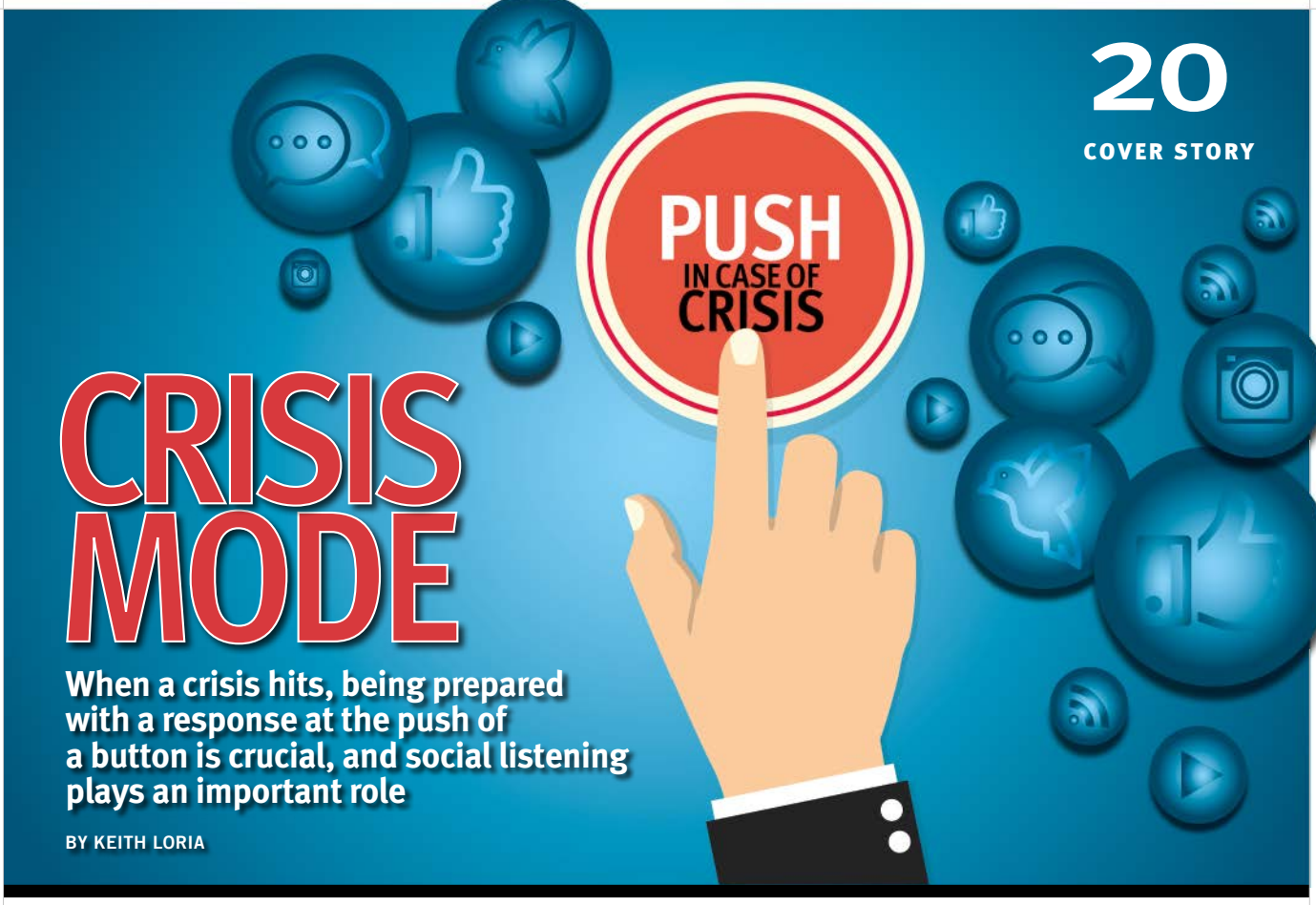

Food Quality & Safety (ISSN 1092-7514) is published 6 times a year in Feb/Mar, Apr/May, Jun/July, Aug/Sept, Oct/Nov, Dec/Jan by Wiley Subscription Services, Inc., a Wiley Company, 111 River St., Hoboken, NJ 07030-5774. Periodical postage paid at Hoboken, NJ, and additional mailing offices.
Print subscriptions are free for qualified recipients. Annual paid subscriptions are available to all others for $206.
For subscription questions in the U.S., call 844-862-9286. For outside the U.S., call 856-255-5537.

Food Quality & Safety is a proud member of: United Fresh Produce Association
APEX, Folio Ozzie, and ASBPE award winner for editorial and graphics excellence.
POSTMASTER: Returns and address changes to *Food Quality & Safety* magazine, PO Box 986, Levittown PA 19055-0986

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From The Editor

I'm excited to announce that Food Quality & Safety magazine has recently added two well-known Co-Industry Editors to its team: Purnendu C. Vasavada, PhD, and Richard Stier.

Most notably, Dr. Vasavada is a Professor Emeritus of Food Science at the University of Wisconsin-River Falls, and the principal and managing member of PCV & Associates. He is a lead instructor for Preventive Controls Qualified Individual (PCQI) training for Human Food and for the Foreign Supplier Verification Programs. Dr. Vasavada previously served as coordinator of the Food Safety Preventive Controls Alliance.

Stier works as an international consulting food scientist, dealing with a wide range of processing systems and products. In addition to being a food safety, GMP, and quality systems auditor, he is also certified as a seafood and meat and poultry HACCP instructor, and is a PCQI instructor.

Throughout the years, many of you have sat in on their seminars/workshops at conferences, read their articles/book chapters/peer-reviewed papers, or even have had the opportunity to work with them individually as they shared their knowledge in improving your company's food systems. And now I'm happy to say that these two longstanding food safety advocates will be contributing their expertise to help strengthen the content of Food Quality & Safety. Numerous professional affiliations, societies, and honors will come in handy as both experts will share their insights and opinions on various topics, such as regulations, microbiology, quality assurance, and sanitation.

Dr. Vasavada and Stier will debut their editor column in the next issue. Although you will no longer "see" me in the front of the magazine, I'll still be behind the scenes working with our new Co-Industry Editors to ensure that our publication remains your go-to resource for delivering practical information on producing safe, quality food products.

Please join me in congratulating them in their new roles!

Marian Zboraj
Professional Editor

Purnendu C. Vasavada

Richard Stier

As always, you can continue emailing me your thoughts and comments pertaining to the industry, or our publication, at mzboraj@wiley.com.

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Food Quality & Safety
FARM TO FORK SAFETY

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Reprints: E-mail kpotuzni@wiley.com

Printed in the United States by Dartmouth Printing, Hanover, NH.

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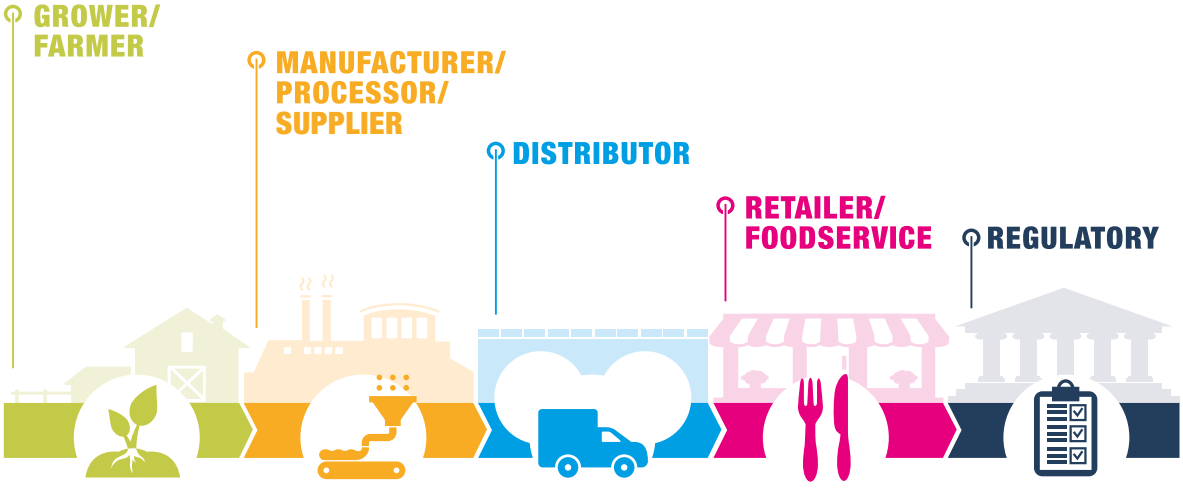

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NEWS & NOTES

At USDA...

USDA's FSIS proposes to amend the egg products inspection regulations by requiring official plants that process egg products to develop HACCP systems and Sanitation SOPs and to meet other sanitation requirements consistent with the meat and poultry regulations. FSIS is proposing that facilities will be required to produce finished egg products free of detectable pathogens. The regulatory amendment is also said to remove unnecessary regulatory obstacles to innovation.

According to "Impacts of the 2014-2015 Highly Pathogenic Avian Influenza Outbreak on the U.S. Poultry Sector," a new report from USDA's Economic Research Service, between December 2014 and June 2015, more than 50 million chickens and turkeys in the U.S. died of highly pathogenic avian influenza or were destroyed to stop the spread of the disease. These birds accounted for about 12% of the U.S. table-egg laying population and 8% of the estimated inventory of turkeys grown for meat. In response to this historic animal-disease event, many destination markets for U.S. poultry commodities levied trade restrictions on U.S. poultry exports, distorting markets and exacerbating economic losses.

USDA's FSIS also proposes to amend the federal meat inspection regulations by establishing a new voluntary inspection system for market hog slaughter facilities called the New Swine Slaughter Inspection System (NSIS), while also requiring additional pathogen sampling for all swine slaughter facilities. According to the agency,

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market hogs are uniform, healthy, young animals that can be slaughtered and processed in this modernized system more efficiently with enhanced process control. For market hog establishments that opt into NSIS, the proposed rule would increase the number of offline USDA inspection tasks, while continuing 100% FSIS carcass-by-carcass inspection.

FDA Updates

FDA scientists releases their quantitative risk assessment model using a discrete event framework to quantify and study the risk associated with norovirus transmission to consumers through food contaminated by infected food employees in a retail food setting. According to agency, norovirus is the leading cause of foodborne illness in the U.S. Food employee contact with raw or other ready-to-eat foods is the most common scenario resulting in foodborne norovirus outbreaks. The objective of this risk assessment was to evaluate the impact of prevention strategies and their level of compliance on contaminated food servings and the number resulting infected consumers; and to provide a basis for potential changes regarding Employee Health for the 2017 FDA Food Code.

In other news, the U.S. FDA has released five guidance documents to help importers and food producers meet key food safety provisions mandated by FSMA. Two of these documents, a draft guidance and a Small Entity Compliance Guide, are meant to help industry meet the requirements of the Foreign Supplier Verification Programs (FSVP) regulation. The third draft guidance addresses the term "same level of public health protection" that is used in both the FSVP regulation and the Produce Safety regulation. This draft guidance provides a framework for determining the adequacy of a process, procedure, or other action intended to provide the same level of protection as those required under FSMA for produce and for human or animal food. The fourth guidance is another chapter in the draft guidance that FDA has been issuing to help food processors and manufacturers comply with the regulation implementing FSMA's requirements for hazard analysis and risk-based preventive controls for human food. This chapter is designed to help food facilities comply with the supply-chain program requirements of that regulation. The final guidance announces the agency's intention to exercise enforcement discretion with regard to FSVP for certain importers of grains brought into the U.S. as raw agricultural commodities. More information about these guidance documents can be found at FDA.gov.

Finding the Sources of Foodborne Illnesses

The Interagency Food Safety Analytics Collaboration (IFSAC) releases a report titled "Foodborne illness source attribution estimates for 2013 for Salmonella, Escherichia coli O157, Listeria monocytogenes, and Campylobacter using multi-year outbreak surveillance data, United States." The authors used outbreak data to update previous analyses. CDC estimates that, together, these four pathogens cause 1.9 million cases of foodborne illness in the U.S. each year. The report noted that *Salmonella* illnesses came from a wide variety of foods; *E. coli* O157 illnesses were most often linked to vegetable row crops (such as leafy greens) and beef; *Listeria monocytogenes* illnesses were most often linked to fruits and dairy products; and non-dairy *Campylobacter* illnesses were most often linked to chicken. IFSAC indicates that an attribution percentage for dairy was not included because, among other reasons, most foodborne *Campylobacter* outbreaks were associated with unpasteurized milk, which is not widely consumed, and likely over-represents dairy as a source of *Campylobacter* illness.

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U.S. Approves Chinese Genetically Modified Rice

As reported by Reuters, a rice genetically modified (GMO) by Chinese researchers to resist pests has passed safety inspections by authorities in the U.S., allowing for its sale in the U.S. even though Beijing continues to prohibit planting of any GMO food grain. The rice, known as Huahui 1, was developed by a team at Huazhong University in central Hubei province to resist pests like the rice stem borer. While Chinese authorities granted the strain a safety certificate in 2009, it has never been approved for commercial production. Beijing has spent billions of dollars researching GMO crops but has held back from commercial production of any food grains because of consumer concerns about their safety. Validation of the country's GMO safety testing and products by U.S. authorities could help persuade the government and consumers in China to accept the products at home.

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France's Lactalis Forced into New Recall in Baby Milk Scare

As reported by Reuters in January, French dairy group Lactalis is widening a product recall to cover all baby milk manufactured by a factory at the center of a *Salmonella* contamination. The move comes as the government seeks to contain reputational damage to France's strategic agri-business industry in overseas markets. At least three dozen children have fallen ill in France and at one other in Spain. Lactalis management, indicated the company would recall all infant formula milk products made at its Craon factory that were still in warehouses and on store shelves, regardless of the date of manufacture. The tough measure reflects high-level frustration at the botched handling of the crisis after France's biggest supermarkets, including Carrefour, Auchan, and Leclerc, said that some Lactalis products subject to recalls in December still found their way onto their shelves.

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Retail Food Waste Action Guide

ReFED launches the Retail Food Waste Action Guide, which finds that food waste represents an $18.2 billion opportunity for grocery retailers. Developed in partnership with the Food Waste Reduction Alliance and its members, the guide supports grocery retailers in developing and implementing prevention, recovery, and recycling solutions to help the industry prioritize and accelerate waste reduction activities. It was created with input from more than 30 expert contributors, including major retailers such as Ahold Delhaize USA, Albertsons, Kroger, Publix, Safeway, Target, Wegmans, Walmart, and Whole Foods. The guide finds that, on average, the value of wasted food in retail is equal to roughly double the profits from food sales; prevention solutions such as dynamic pricing and markdowns have the highest profit potential; and new digital technologies such as ride-sharing platforms and chain-of-custody records are being applied to food waste through solutions like dynamic routing and cold chain management.

Business Briefs

SGS of Geneva, Switzerland, acquires **Vanguard Sciences.**

The **American Botanical Council** (ABC)-AHP-NCNPR Botanical Adulterants Program changes its names to ABC-AHP-NCNPR Botanical Adulterants Prevention Program.

Limagrain Céréales Ingredients partners with **Novolyze** to reinforce the microbiological control of its proprietary heat process for flours.

PerkinElmer collaborates with **TeakOrigin** to develop technology that uses a single platform to analyze food for key indicators that determine authenticity, quality, and freshness.

Matrix Sciences acquires **Neumann Risk Services.**

The International Food Protection Training Institute moves to new office in Portage, Mich.

IEH Laboratories & Consulting Group acquires all assets related to the **Sample6** DETECT platform.

GFSI forms public-private partnership with the **Argentinian Ministry of Agribusiness** to work together on a national training program based on GFSI's Global Markets Program.

Diversey unveils new brand identity to differentiate itself in the global hygiene marketplace and reflect its customer-first ethos.

Sterigenics International changes its parent company name to **Sotera Health LLC.** Its three operating companies—Nelson Labs, Nordion, and Sterigenics—will maintain their current names.

Food Safety Net Services opens analytical laboratory for the food and consumables industry in Atlanta, Ga.

The **U.S. FDA** discontinues the **Food Advisory Committee.**

ScanTech Sciences' first Electronic Cold-Pasteurization Center is slated to open and be operational in late Spring 2018.

Washington Report

FDA Rules Tripping Up Food Importers

FSVP violations among most common and expected to skyrocket | BY **TED AGRES**

Despite Foreign Supplier Verification Program (FSVP) regulations having been in effect for only four months during 2017, violations of that rule were among the 20-most common infractions issued by FDA investigators during routine inspections of U.S. facilities during the last fiscal year.

FSVP requires all U.S. food importers (not just those registered with FDA) to develop plans to and actively monitor foreign suppliers' compliance with the Food Safety Modernization Act (FSMA). This year, as more U.S. importers of foreign food products come under FSVP's purview, violations of the rule are expected to skyrocket.

"The first FSVP compliance deadline (May 30, 2017) was only in effect for about four months in fiscal year 2017, and FSVP made its way into the top-20 most frequent inspection violations," says Russell Statman, executive director of Registrar Corp, a consultancy that helps companies comply with FDA regulations.

"With the second FSVP deadline passing in March [2018], I foresee it making its way into the top-5 in fiscal year 2018," Statman tells Food Quality & Safety magazine. (Fiscal 2018 runs from Oct. 1, 2017 through Sept. 30, 2018.) Until last year, FDA did not inspect U.S. importers unless the firm also processed food. "With the advent of FSVP, importers now will be introduced to this process as FDA inspects for compliance with the new rule," he says.

Late last year, FDA's Office of Regulatory Affairs released summaries of routine field inspections and enforcement activities conducted during fiscal year 2017 (Oct. 1, 2016 through Sept. 30, 2017). The summaries identify the statutory areas under which thousands of Form 483s were issued to companies having conditions or practices that may violate FDA requirements. As in previous years, the following were the top-five areas in terms of number of citations issued:

1. Lack of effective pest exclusion/screening. Not taking effective measures to protect from contamination from pests or excluding pests from food production areas (541 violations).

2. Sanitation monitoring. Not monitoring sanitation conditions and practices frequently enough to conform to current Good Manufacturing Practices. Includes conditions of food contact surfaces and measures to prevent cross-contamination (516 violations).

3. Plant cleanliness. Failing to maintain cleanliness of the premises or the facility is not constructed in such a way as to allow proper sanitation or maintenance (368 violations).

4. HACCP plan implementation. Seafood or juice manufacturers fail to implement procedures in their HACCP plans (162 violations).

5. Reasonable precautions. Failing to take precautions to prevent production procedures from contaminating food. Reasonable precautions include monitoring food processing time and temperature or monitoring freezing and heat processing (146 violations).

"Failure to develop an FSVP" was cited 108 times last year, placing that violation among the top-20, even though the rule was in effect for only four months.

"It's apparent that FDA is checking for FSVP compliance, and non-compliance is a prohibited act," Statman says. Food imported by a non-compliant importer is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act.

What FSVP Requires

FSVP requires U.S. importers to verify that the food they import meets the same safety standards as domestically produced items. U.S. importers are required to develop, maintain, and follow a foreign supplier verification plan (also called an FSVP) for each food they import, unless an exemption applies (such as for juice and seafood, which are covered by separate HACCP regulations, and certain low-acid canned foods).

Each FSVP must include a hazard analysis, an evaluation of risk and supplier performance, documented supplier verification activities, and a plan for corrective

action, if needed. Multiple foods from a single supplier or multiple units of a single food from multiple suppliers each require individual FSVPs.

Companies have some flexibility in determining appropriate verification methods, depending upon the hazards needing to be controlled, the foreign supplier's food safety record, and other factors. Verification methods could include onsite audits and inspections, sampling and testing, and review of the supplier's safety records, says Hank Karayan, global FSMA program director at SGS, a multi-industry inspection, verification, testing, and certification company.

Importers must also designate a "qualified individual," defined as someone possessing either appropriate training or job experience with developing a food safety system, to develop and perform FSVP activities for each imported food item. Importers that do not have a qualified individual on staff may outsource FSVP development to a third party, such as Registrar Corp, or outsource verification activities to companies such as SGS.

FDA has staggered FSVP compliance dates based on the size of the foreign supplier (not the size of the U.S. importer) and the dates of other FSMA regulations to which the foreign supplier would be subject. This was to give U.S. importers time to become familiar with their legal responsibilities and develop their FSVPs. It also aligns FSVP compliance dates with other FSMA regulations, particularly the produce safety and preventive controls rules for human and animal food.

"We linked the FSVP compliance dates to the other FSMA rules because we wanted to minimize the likelihood that an importer would be required to comply with the FSVP regulations before its supplier is required to comply with other FSMA safety regulations," explained Sharon Mayl, senior advisor for policy in FDA's Office of Foods and Veterinary Medicine.

The first FSVP compliance date was May 30, 2017 for U.S. companies that import food from large foreign suppliers or from suppliers not subject to the preventive controls or produce safety rules. For foreign suppliers that are subject only to the preventive controls rule, the next importer compliance dates are March 19, 2018 for "small businesses" (defined as foreign suppliers with fewer than 500 full-time employees), and March 18, 2019, for "qualified facilities" and "very small businesses" (foreign suppliers with less than $1 million in average annual sales).

For importers whose foreign suppliers are subject only to the produce safety rule, the compliance dates are July 29, 2019 for small business, and July 27, 2020 for very small businesses. All other businesses must comply starting July 26, 2018.

"Remember that, unlike traditional facility inspections, FSVP inspections are based on the review of records, rather than observations of food production," FDA's Mayl explained. Most FSVP inspections will occur at the importer's place of business, where the investigator will ask to see the importer's FSVP records. In most cases, if deficiencies are found, the importer will get an opportunity to correct them.

"Our focus right now is on supporting compliance, except for problems that pose a danger to health or reflect intentional disregard for legal responsibilities," Mayl said.

But companies that receive a citation for not having a FSVP may find themselves on FDA's radar. This is because the agency's risk analysis algorithms may automatically assign companies with prior deficiencies a higher risk score, increasing scrutiny and the potential for enforcement actions, Registrar Corp's Statman says. "The best way to stay out of trouble with FDA is to stay out of trouble with FDA," he says. "But if an importer or processor develops a clean record early, later deficiencies may have less effect."

Beginning this year, U.S. importers can apply to register in FDA's Voluntary Qualified Importer Program (VQIP), which offers expedited review and entry into the U.S. of food from foreign companies that have been certified by auditors under the Accredited Third-Party Certification rule. "Expedited shipment entry gives importers incentive to adopt robust management of the safety and security of their supply chain," said Doriliz De Leon, a consumer safety officer in the Food Adulteration Assessment Branch in FDA's Center for Food Safety and Applied Nutrition.

To be accepted into VQIP, U.S. importers must not only comply with FSVP but also develop and implement a Quality Assurance Program, which includes additional written policies and procedures for food safety and security, including for transportation and food defense. Enrollment in VQIP "will be particularly helpful for those (U.S. companies) importing perishable products or using 'just in time' processing, in which ingredients must be at a food facility at a certain time in the manufacturing process," De Leon explained.

'Enforcement Discretion'

While most FSVP and FSMA provisions have been coming into effect under previously announced timelines, on Jan. 4, 2018 FDA announced it would not be enforcing certain provisions of four FSMA regulations because they would create unanticipated burdens on industry and government. Among the four is an FSVP provision that equates food contact substances, such as packaging and food holding material, with being "food." Because these substances are already subject to FDA premarket review and other regulations, "FDA does not intend to require importers of food contact substances to comply with FSVP."

"FSMA has many tentacles and impacts multiple parts of the food industry," says David Acheson, MD, founder and CEO of The Acheson Group and a former associate FDA commissioner for foods.

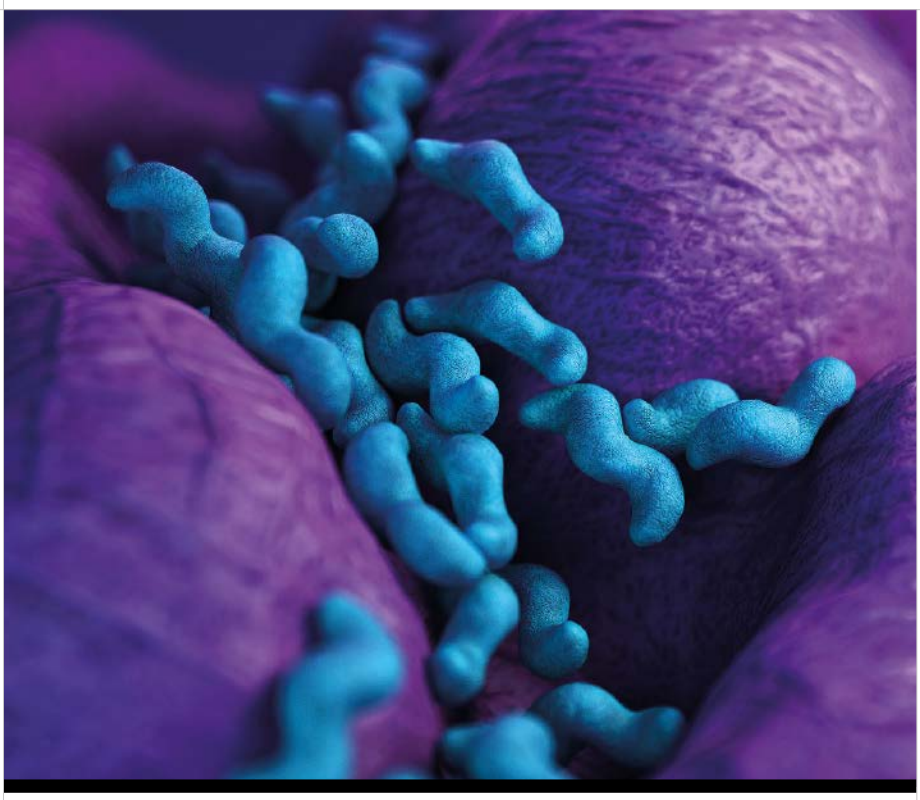
For example, FDA can disallow import of food from a foreign supplier that has refused to be inspected. "And that 'refusal of inspection' doesn't just mean answering FDA's knock, it means anything from not responding to FDA's request within 24 hours, to agreeing to an inspection start date then requesting a later date without reasonable explanation, to a foreign government not allowing the FDA investigator into the country," Dr. Acheson explains.

It could take at least one year before FDA can return to do the inspection, so Dr. Acheson recommends that U.S. companies alert their suppliers to the importance of not refusing an FDA inspection.

"It has been our impression that many foreign suppliers really don't understand the impact of FSMA," Dr. Acheson says. "So, making sure that they don't find themselves on a 12-month import alert could be critical to protecting your supply chain integrity as well as their business." ■

Agres is an award-winning writer based in Laurel, Md. Reach him at tedagres@yahoo.com.

Pathogen Patrol



Kudos to *Campylobacter*?

Advances in testing, identification, and control measures continue for the world's most successful instigator of foodborne illness

BY **LINDA L. LEAKE, MS**

Like it or not, congratulations are in order for *Campylobacter*. This ubiquitous organism captured first place honors on the CDC's list of organisms responsible for foodborne illness in the U.S. in 2016, with 8,547 cases reported on CDC's Foodborne Diseases Active Surveillance Network (FoodNet).

In addition to this overall number of reported campylobacteriosis cases, *Campylobacter* ranks among foodborne pathogens as the third leading cause of hospitalizations (with 1,082 out of 5,512 hospitalizations, 19 percent of hospitalizations) and the fifth leading cause of death (10 deaths attributed to *Campylobacter* out of 98 deaths attributed to all foodborne pathogens) in the U.S. in 2016, according to FoodNet's April 21, 2017 issue of the Morbidity and Mortality Weekly Report.

Of note, this is the first time the report includes in the total number of infections in FoodNet sites those foodborne bacterial infections diagnosed only by rapid diagnostic tests, which are described collectively as culture-independent diagnostic tests (CIDTs).

Of the 8,547 total 2016 *Campylobacter* cases, 5,782 cases were confirmed with culture and 2,765 cases were detected via CIDT alone.

Since CIDTs do not require isolation and identification of living organisms, they can be conducted more rapidly and yield results sooner than can be achieved with traditional culturing methods, says Robert Tauxe, MD, director of CDC's Division of Foodborne, Waterborne and Environmental Diseases.

Dr. Tauxe is quick to point out that, while CIDTs can have immediate benefits for treatment, they don't collect information needed to determine if an infection is antibiotic-resistant or if it is linked to an outbreak. And, while positive results on rapid tests can be followed up by culture-based tests to get detailed data, they often are not.

"Public health officials need foodborne-illness trend data to monitor progress toward making our food supply safer," Dr. Tauxe emphasizes. "Thus, it's important that laboratories continue to do follow-up cultures on CIDT-positive patients."

Whole Genome Sequencing

Starting in 2018, the CDC plans to begin using whole genome sequencing (WGS) in the PulseNet network to "fingerprint" *Campylobacter*. This work flows from the pilot program CDC launched in 2013 to implement WGS for *Listeria* subtyping and control.

"Using WGS for *Listeria*, we found more outbreaks than ever, traced them to new and unsuspected sources, and found new points where prevention can be improved," Dr. Tauxe relates. "We are anticipating that the same thing can happen with *Campylobacter* and other foodborne bacteria, as we apply WGS methods for public health surveillance."

Ann-Katrin Llarena, DVM, PhD, a researcher with the University of Helsinki, Finland, believes WGS is set to emerge as the typing method of choice for *Campylobacter jejuni* (*C. jejuni*) outbreak investigations worldwide, and it has the potential for implementation in routine surveillance.

"However, several issues regarding epidemiology and genomic diversity need to be addressed before WGS can become a useful and reliable working tool in the public health sector response to campylobacteriosis," Dr. Llarena says.

In an article titled "Whole-Genome Sequencing in Epidemiology of *Campylobacter jejuni* Infections," published in the May 2017 issue of the Journal of Clinical Microbiology, Dr. Llarena and her co-authors point out that, even though *C. jejuni* is one of the most frequent causes of bacterial gastroenteritis globally, the epidemiology of this pathogen is only partially understood, and shedding new light on this area is difficult since most cases are sporadic and go unreported.

"Several projects aim to integrate WGS in routine surveillance and outbreak investigations," Dr. Llarena mentions. "One of these, the European consortium INNUENDO, co-funded by the European Food Safety Authority (EFSA), is aiming to deliver a standardized, cross-sectional framework for integration of bacterial WGS in routine surveillance and epidemiological investigations."

Windy City Symposium

Some 50 scientists representing academia, government, and industry from the U.S. and European Union (EU) gathered in Chicago on Dec. 3, 2017, for the first National *Campylobacter* Symposium.

Supported by USDA National Institute of Food and Agriculture (NIFA), presentations at this event contrasted U.S. and EU approaches to reducing the burden of *Campylobacter* in commercial poultry and regulatory tolerance thresholds, says Max Teplitski, PhD, NIFA's national program leader in food safety and microbiology.

"Much of the current U.S. industry efforts focus on the post-harvest reduction," he relates, "while in the EU, where sanitizers for carcasses are either entirely banned or severely restricted in use, most of the *Campylobacter* reduction efforts take place on the pre-harvest end of the production."

Regulatory guidance for *Campylobacter* in the U.S. and EU are, perhaps, reflective of these different approaches, Dr. Teplitski notes. "While U.S. poultry producers aim to almost completely eliminate this pathogen from poultry products that reach consumers, often achieving up to 6 to 7 log reduction, the EU aims to maintain a threshold of less than 1,000 colony-forming units per gram of raw commercial product," he elaborates.

Campy Consumer Research

Researchers at Tennessee State University (TSU), Nashville, are completing an ambitious six-year project, funded by a $2.4 million NIFA grant, focused on reducing illnesses from *Campylobacter* (and *Salmonella*) by improving consumer storage, handling, and preparation of raw poultry and poultry products.

"Working with Kansas State University and RTI International, we began our project by conducting focus groups and

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a nationally representative Web-enabled survey to characterize consumer practices and awareness and understanding of existing food safety messages," says project director Sandria Godwin, PhD, a TSU food science professor. "This research was supplemented by observational and laboratory-based studies to address gaps in the scientific literature. Our studies were designed to describe shopping behavior and home storage practices and the risk of cross-contamination, assess the risk of extended consumer storage of fresh and liquid eggs, and determine temperatures of current consumer cooking practices of poultry products and eggs. We also identified risky practices and used the results to develop science-based and consumer-focused messages addressing these practices."

Dr. Godwin says the study yielded a multifaceted educational program for youth aged 12 to 18 and adults. "The curriculum and print resources are being designed so that other food safety educators can easily use them," she points out. "The curriculum is downloadable from the Web and also available on a USB."

Don't Wing It!, another TSU *Campylobacter* educational program funded by NIFA, targets millennial parents and older adults. The site also has a section for grocers with food safety handouts and promotional items.

Nanotechnology Tool

In August 2017, Fur-Chi Chen, PhD, a TSU research professor, completed a NIFA-funded project aimed at developing and validating a highly sensitive surface plasmon resonance (SPR) sensor combining antibody-functionalized magnetic nanoparticles for rapid detection of *Campylobacter* in raw poultry products.

"We used magnetic nanoparticles, which were functionalized using monoclonal antibodies specific to *Campylobacter* surface antigens, to separate *Campylobacter* from food matrixes," he relates. "The magnetic nanoparticles used in the protocol functioned not only as probes to selectively bind and separate *Campylobacter*, but also as an amplification agent to enhance the SPR signal."

The use of magnetic nanoparticles in the SPR protocol provided three orders of magnitude in the improvement of sensitivity toward *Campylobacter* compared to the regular SPR sensor with a direct detection format, Dr. Chen reports.

"The SPR sensor we developed has the potential to provide a simple, low-cost, and sensitive method for detection of *Campylobacter* in poultry products," he predicts.

Global Distinction

Not only does *Campylobacter* have bragging rights in the U.S., this pesky bug's influence and Number 1 status is global. The World Health Organization considers the relentless Gram- negative organism to be the most common bacterial cause of human gastroenteritis in the world.

Campylobacter is identified as the leading pathogen causing foodborne bacterial infections in the EU, according to EFSA and the European Centre for Disease Prevention and Control. From their most recent report, in 2015 *Campylobacter* continued to be the most commonly reported gastrointestinal bacterial pathogen in humans in the EU. The number of reported confirmed cases of human campylobacteriosis was 229,213.

"In August 2017, the European Commission issued an Amendment of EU regulation 2073/2005 on microbiological criteria for foods, stipulating EU-wide process hygiene criteria for broiler carcasses, with a target value of 1,000 colony forming units per gram of pooled neck skin," says Mieke Uyttendaele, PhD, a microbiologist at Ghent University in Belgium. She is a co-author of "Sense and Nonsense of Microbiological Analysis of Foods: Guidelines for the Interpretation of Results of Microbiological Testing of Foods," available in March 2018.

Trojan Horse Research

Researchers at Kingston University, London, England have shown how *Campylobacter jejuni* can infiltrate amoebae and multiply within their cells—protected inside the amoebae from harsh environmental conditions.

"This is significant since *Campylobacter* and amoebae often exist in the same environments, drinking water for chickens on poultry farms, for example," says Kingston PhD student Ana Vieira, the project leader. "The amoeba may act as a protective host against some disinfection procedures, so the findings could be used to explore new ways of preventing the bacteria's spread by breaking the chain of infection."

"Being protected inside amoebae allows *Campylobacter* to thrive, then to escape the amoebae cells in larger numbers," says Kingston University microbiology professor Andrey Karlyshev, PhD, the study supervisor. "Because amoebae are widespread, we have shown how *Campylobacter* are able to use them as a Trojan horse for infection of the food chain. Otherwise *Campylobacter* wouldn't survive, as they are very sensitive to the environment."

Another research direction in Dr. Karlyshev's lab is the investigation of possible applications of probiotics for treatment and prevention of *Camylobacter* infection in humans, as well as for potential elimination of these bacteria from poultry.

"In particular, the results of a study, '*Lactobacillus fermentum* 3872 as a potential tool for combatting *Campylobacter jejuni* infections,' reported by Burhan Lehri, a PhD student and the project leader in our lab, suggest that the probiotic bacterium *L. fermentum* can compete with *C. jejuni* for binding to host cell receptors (collagen), which may result in competitive exclusion of the pathogen," Dr. Karlyshev explains. "Although these experiments were conducted *in vitro*, they provide a proof of principle of the potential application of beneficial bacteria for fighting these infections."

"Theoretically, the probiotic can be used alongside rehydration therapy in humans to reduce the severity of infection," Lehri notes. "*L. fermentum* 3872 may also be utilized as a prophylactic in individuals traveling to areas that have a high incidence of *C. jejuni* related infections. Future studies may be conducted to determine the effect of *L. fermentum* 3872 on poultry, as well." ■

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For extended online coverage of *Campylobacter*, go to the February/March 2018 issue at www.FoodQualityandSafety.com.

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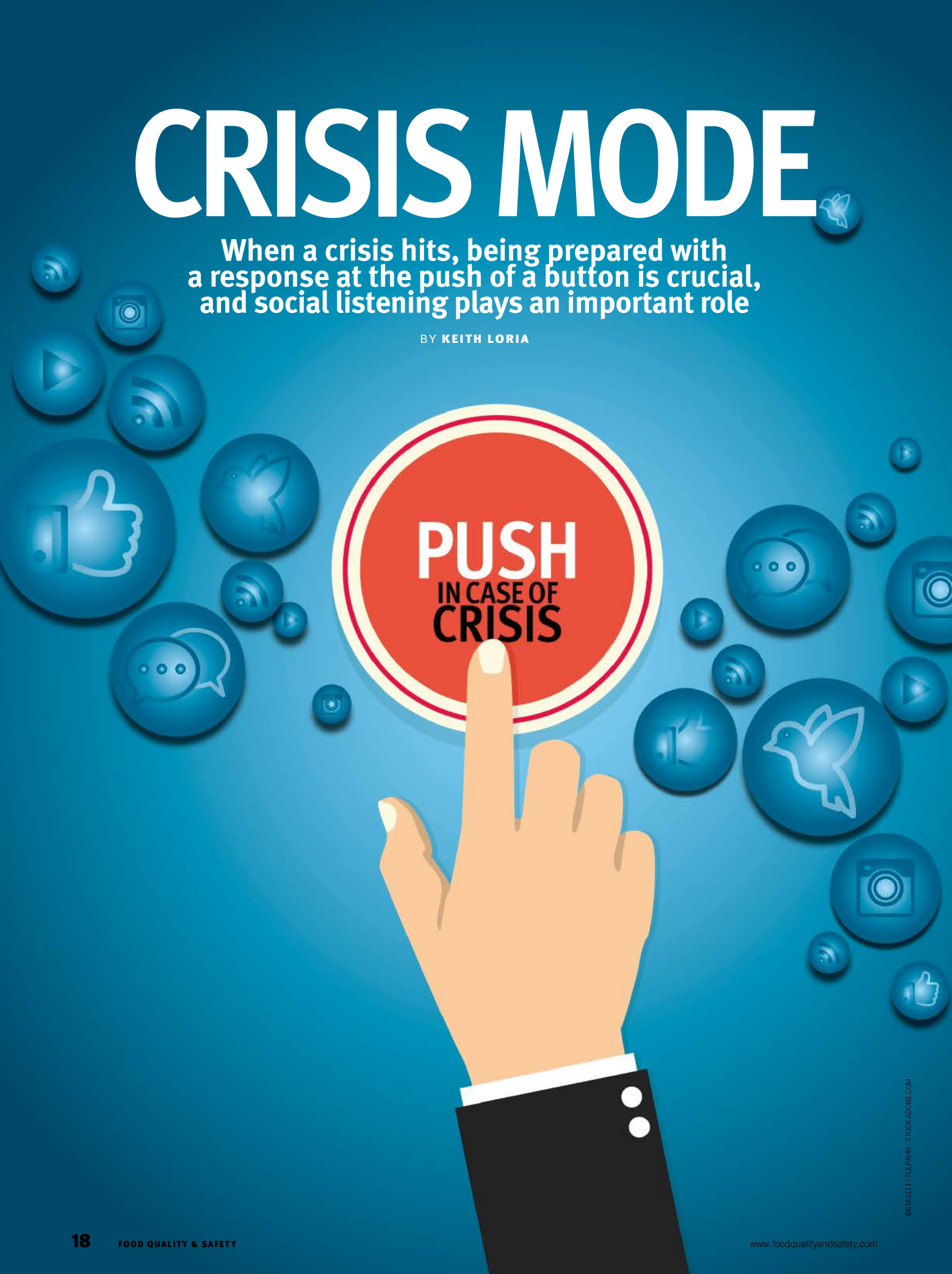
CRISIS MODE

When a crisis hits, being prepared with a response at the push of a button is crucial, and social listening plays an important role

BY **KEITH LORIA**



In this age of instant information, news about restaurant fiascos and food recalls can be spread to hundreds of thousands of people in minutes, so when a food safety crisis hits, it's essential that a company is prepared with a response and communicates with the public immediately.

After all, when news of a crisis spreads without an adequate and timely response, it can damage a successful brand's reputation and negatively impact customer loyalty, even if the rumors are false.

Sue Reninger, client brand strategy, managing partner for RMD Advertising, Columbus, Ohio, states the strategies used in managing a food crisis cannot and should not waver as the latest buzz dictates.

"Responding to a crisis requires pre-planning, carefully crafted messaging, and a calm, cool demeanor," she shares. "All responses within the food business are representative of the brand (and often the family that owns the food brand). Being proficient in food crisis management is a critical discipline for any food brand or agency that has a hand in the food industry."

By fine-tuning a food crisis strategy, she adds, brands can ensure they continue to serve the organization well and protect their public profile while helping to instill trust between the brand and its consumers.

Companies that used one of the more popular social media channels when informing consumers of product or packaging problems suffered from less of a negative sales reaction than organizations that didn't have Facebook or Twitter accounts.

The Rise of Social Listening

Sean Smith, executive vice president and head of reputation management for Porter Novelli, Berkeley, Calif., notes that speed has always been important, but it's even more so now, emphasizes that it's critical to acknowledge what is going on and work to minimize the impact.

There's no better way, he offers, than social listening, which is free and delivers extremely valuable insights direct from consumers.

"Consumers were always talking about your brand. It's an amazing gift to be able to listen in on that conversation—and to participate in it," he says. "Constant monitoring of social channels helps brands understand the real-time conversations that are taking place. Whether in times of a crisis, or not, it's important for brands to be aware of consumer chatter."

Online communities are changing the way food-related businesses research and communicate with their target audiences. Being unaware of what people are saying about a company, farm, restaurant, or other business in a crisis on social media is risky business.

Smith says there is no other method of contacting customers that combines the benefits of cost effectiveness, speed, and engagement. That's why a growing number of companies are turning to social listening to contain a crisis, prevent the spread of misinformation, and minimize the impact to the bottom line.

Susan M. Tellem, a partner at Tellem Grody Public Relations, Inc., Malibu. Calif., leads the crisis team and the food issues group for the company. She feels when you "listen" to social media, a company can correct misinformation quickly, find out who is friend or foe, do "live" messages from the head of the company, and rapidly make changes in strategy if the current one is not working.

"Typically, recall success rates fall below 30 percent, leaving huge amounts of potentially dangerous products out and available in the marketplace," she says. "Social media has an important role to play to make this process more efficient and improve success rates."

Christof Bentele, global head of crisis management for Allianz Global Corporate & Specialty, Novato, Calif., says clients now use social media listening platforms to pick up on issues faster than ever before to get ahead of a crisis.

"There is now so much data constantly being created about an organization that it's now critical to incorporate technology-based solutions to ensure critical issues are flagged prior to their development into a crisis," he says. "Social media engagement is no longer an option for a company—if it does not have a strategy, the organization will lose control over its content being shared about the business."

Neil Steinberg, vice president, public relations and communications for Dataminr, a New York-based technology company that discovers high-impact breaking information from social media in real time, opines that brands are looking at the general conversation on social media to get a better grasp on how it's evolving in real time, both positively and negatively.

"Additionally, they're focusing on specific hashtags—how many people are retweeting and interacting with a specific hashtag, and how far their message or campaign is getting out there," he says. "Supply chain, employee behaviors, and sub-standard prep conditions are among the key triggers as it relates to food safety issues. For food brands, many of these issues can be discovered through social listening."

The ability to monitor, capture, and react to this content early allows brands to kick-start a crisis response and mitigate

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A study by Lithium revealed that 78 percent of people who complain to a brand via Twitter expect a response within an hour.

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risk. This also allows them to determine if the issue is specific to a certain store as it relates to a national chain (e.g. the Buffalo Wild Wings chicken head issue), an employee, or something with a larger scope, such as a supplier that may trigger a regional or even a national recall.

"As it relates to food and beverage crises, social media can both discover, validate, and ultimately respond to a crisis," Steinberg says. "While social media is often the tripwire of a crisis, embracing the medium enables brands to get in front of a situation from a public affairs and customer relations perspective before it spirals out of control."

Additionally, from a customer perspective, customers are utilizing social media more than ever to voice their complaints and highlight issues in a public manner, which adds increasing pressure for brands to act quickly and efficiently.

A Stronger Connection

No matter the social network (Facebook, Twitter, Yelp, etc.), blog, or online forum, the social web is offering customers a more personal connection, which is why social media involvement is vital in a crisis.

"Hearing about a crisis before the issue has snowballed and developed is important because consumers can be protected and reassured that they are doing business with a firm that cares," Bentele shares. "If managed effectively, social media channels enable a company involved in a crisis to manage the issue more closely and move an issue into an offline environment where the full facts can be identified."

One example of where social media formed part of the process was when the Greek-style yogurt company Chobani had an issue on Aug. 26, 2013. Customers complained that products were exploding and that mold was found inside, and more than 30 social media stories were posted about the issue that day.

Chobani quietly communicated the issuance of a voluntary withdrawal to stores, instructing them to remove the affected products. It wasn't until September 5, however, that Chobani addressed the problem head on and set up an aggressive campaign.

"A Facebook post was issued reporting that a decision had been made to remove yogurt from selected stores due to 'isolated quality concerns.'" Bentele says. "To note, carrying out a withdrawal rather than a recall did lead to some criticism on social media channels as the company was perceived as not having taken the issue seriously enough."

In March of 2015, the outbreak of the H5N2 avian influenza (bird flu) was the largest in U.S. history and ravaged the Midwest's poultry population. Steinberg notes Dataminr was able to provide real-time notifications as the outbreak impacted supply, production, and sales for commercial poultry processing and biotech companies. These notifications kept things from escalating due to false information spreading.

A report in socialmedia.com revealed that 71 percent of consumers who have had a positive social media service experience with a brand are likely to recommend it to others. Companies that used one of the more popular social media channels when informing consumers of product or packaging problems suffered from less of a negative sales reaction than organizations that didn't have Facebook or Twitter accounts.

Even so, Smith recommends that when consumers raise a food safety related issue on social media, companies should take the conversations offline.

"Food safety and customer support teams need to work directly with the consumer to best understand the issue," he says. "This involves around-the-clock monitoring on social media channels, maintaining a consistent voice across various channels, and leading with the facts—whether that be a press release, respective response, or customer letter."

The Downside of Social Media

Unfortunately, there are some negatives to relying on social media for communication with consumers. For one, social media channels are open to hacks and

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In the fast-paced era we live in and 24-hour news cycle, companies need to be monitoring the conversation on social media and be proactive about handling any direction that it might take.

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hoaxes, which can be very damaging to a brand. And in the social media world, it's more about a company being "guilty until proven innocent," which makes it critical to manage negative messaging very carefully.

A study by Lithium revealed that 78 percent of people who complain to a brand via Twitter expect a response within an hour.

Winston Churchill once said, "A lie gets halfway around the world before the truth has a chance to get its pants on." And that was before the advent of the Internet!

The speed at which a food safety incident escalates can get out of control. For example, on Dec. 8, 2017, a customer of Primark complained about a fire risk issue relating to a low-cost candle and this single complaint was responsible for 250,000 shares among all major media streams within a matter of hours.

"As an uncontrolled media source, it's difficult for all parties to determine what is and isn't fact," Bentele notes. "As such, it's critical for companies to have the marketing and PR expertise to help manage social media issues effectively. Honest information will often get lost amongst sensational and inaccurate information."

Reninger believes the social space has been both a curse and a gift in the area of food crisis. While the messages and conversations being shared by consumers about a brand are more frequently brought to light, being part of the conversation—or at least being aware of it—is a powerful benefit that has not always available to food brands.

"Social listening should be an active and diligent practice of food brands, as food can either nourish us or serve as a

A Dangerous Disconnect: A Need for More Consumer Engagement

While food companies, federal regulatory agencies, and farmers are held responsible for ensuring the health and safety of food, not all are trusted to get the job done, according to new research from The Center for Food Integrity (CFI). The findings illustrate a dangerous trust deficit that breeds increased public skepticism and highlights the need for increased consumer engagement by the food system.

"If you're held responsible and trusted for ensuring safe and healthy food, you are seen as a credible source," said Charlie Arnot, CEO of CFI. "However, if you're held responsible but not trusted, that's a dangerous disconnect that can't be ignored."

Federal regulatory agencies are held most responsible for ensuring safe food, following by food companies and farmers, according to the survey. However, when it comes to trust, federal regulatory agencies rank eighth and food companies rank last on a list of 11 choices.

"A lack of trust can result in increased pressure for additional oversight and regulations, rejection of products or information, and consumers seeking alternate, and perhaps unreliable, information sources," said Arnot.

The research urges farmers and food companies to engage consumers in a way that addresses their underlying concerns. "Consumers want to know that farmers and food companies share their values, so simply providing facts or information isn't enough," said Roxi Beck, director at CFI. "Meaningful engagement can be a game-changer."

Transparency is a powerful trust-building tool, she said, and can be achieved in many ways, "ranging from photos and videos to blogs that invite questions."

Segmenting by influencer audiences, including moms, millennials, foodies, and early adopters, CFI's research surveyed U.S. consumers on more than 50 topics including most important issues, trusted sources, purchasing behaviors, pressures impacting food choices, and attitudes on farming and food manufacturing.—*FQ&S*

toxin," Reninger says. "The earlier a brand knows about a concern or crisis, the better able it is able to get involved and be a driving part of the solution."

Preparing for Action

A recall typically takes everyone involved by surprise—it's a sudden, unplanned event, which is why Tellem notes a company can reduce the fallout by having a crisis plan in place.

"It doesn't need to be comprehensive, especially if that means you won't make any plan," she says. "It needs to be a clear roadmap to follow when the bad thing happens. You are more likely to crack it open and follow it if it is succinct and easy to implement. You will need a top to bottom survey of past incidents and what could go wrong today."

Team members involved should be those who can think on their feet, have relevant experience, and are close geographically to the business. She also suggests training the spokesperson (and a backup) with a professional media coach by holding on-camera rehearsals and practicing message points.

According to Bentele, companies need to have a robust system in place ready to go if a food safety issue were to pop up, and it needs to be very clear about the company's understanding of what would be considered as an online crisis, and potential options and preparations to be considered for each.

"Establish a crisis team with clearly defined roles and responsibilities and ensure your business has access to marketing and social media expertise," he says. "If this isn't available internally, consider an outsourced provider to assist with strategic planning and support."

He also suggests regularly running through crisis exercises and drills with the response team and considering including complex social media issues, such as false posts and the spread of misinformation.

"Carry out a full analysis of your worst-case scenarios and engage media liaisons for these, should the worst occur," Bentele says. "Ensure that when you do encounter a crisis, all parties are secure in their assigned roles. Training and preparation is critical; the businesses that survive crisis issues do not remain silent and will engage with their customers to regain their trust."

Still, more needs to be done. A recent study on children's products by the consumer group Kids in Danger found that only 25 percent of manufacturers with a Facebook page use it for product recall news.

In the fast-paced era we live in and 24-hour news cycle, companies need to be monitoring the conversation on social media and be proactive about handling any direction that it might take.

"With limited resources, media are becoming increasingly reliant on social media for their storytelling," Steinberg says. "Frequently, as food-related social media posting 'goes viral,' a media outlet will directly reach out to the poster asking permission for usage, an interview, or other engagement. Seeing these interactions provides brands with an opportunity to engage with both the media and an unsatisfied customer, and be proactive in their crisis response." ■

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HOW TO HANDLE FOOD RECALLS IN THE DIGITAL AGE

Best practices in making recalls more efficient and manageable to avoid reputational damage

BY **PETER GILLETT**

Food recalls often leave a bad taste in your mouth in more ways than one. In addition to being a public health issue, food recalls also present economic issues. A joint study by the Food Marketing Institute and the Grocery Manufacturers Association found that the average cost of a recall to a food company is $10 million in direct costs.

If an individual or group of people decide to sue a company over a food recall, the legal fees can add up quickly. Additionally, manufacturers could face government fines. In 2015, ConAgra agreed to pay $11.2 million in fines and forfeitures connected with the charge that it shipped contaminated peanut butter linked to a 2006-2007 nationwide outbreak of *Salmonella* poisoning.

In addition to lasting financial effects, poorly managed product recalls can have devastating consequences on a company's reputation, market share, and bottom line. A Harris Poll found that 85 percent of Americans would get angry if a company has a crisis or issues a product recall. However, there is no data that can exactly predict how high food recall costs might climb. The scale of a recall as well as how it's handled will have the most lasting impact in the minds of consumers.

Timing is Everything

News of a food recall can spread rapidly. According to a Freshfields Bruckhaus Deringer survey, 28 percent of all crises spread to international media within one hour, 69 percent spread to an average of 11 countries within 24 hours.

With so many aspects of organizations moving away from paper and into the digital age, it seems that the management of product recalls hasn't quite kept up. Food recalls are serious tasks for any company to undertake, which is why they can't be managed with outdated processes, such as spreadsheets and paper responses.

Modernizing recall management process results in: accurate and up-to-date customer data stored on modern customer relationship management (CRM) systems; fast and inexpensive notifications; easy response options for customers, and automated response reporting dashboards to show performance and hopefully conformance as a result. So how can manufacturers utilize digital platforms to make food recalls more efficient and manageable?

Dedicated Recall Management

Food recalls can be managed seamlessly and efficiently on a dedicated recall response database. This eliminates the need for complex, manually updated spreadsheets and other paper documents, and provides an accurate system to produce up-to-the-minute reports at the touch of a button. All of your customer information is stored in one centralized place with access available across departments for internal key users. This is then updated automatically as customers are notified and when they respond.

Digital Response

Social media has changed the speed at which organizations must respond. It has provided the public with a very easy way to vent their anger, which can then escalate at significant speed. Social media posts can quickly transform into headline headaches in traditional media outlets. However, this same tool can also allow manufacturers to quickly manage responses and handle a negative situation effectively. This is why having a digital channel strategy ready to follow is so vital.

When a recall occurs, the Consumer Product Safety Commission typically requires that social media notifications be included in corrective action plans. Steps for a product recall digital response include:

- Provide a dedicated URL in your notifications to allow your stakeholders to respond securely online;
- Allow these responses to be automatically added into your dedicated recall database, and attached directly to each contact's record;

- Avoid the potential risk of human error when manually entering data from paper responses; and
- Build up a seamless workflow, from notifications to responses and follow-up, thus simplifying the whole process of managing recall communications.

Digital tools like marketing automation and social media monitoring provide quick communication and gain immediate stakeholder perception and feedback. In addition, they enable you to convey your message to customers and show that you are present and fully engaged with them.

Accurate Reporting

When a food recall occurs, manufacturers not only have to face the public, but they typically have to report to a government agency. Recall authorities often request that companies dealing with a recall submit status reports biweekly (or at least monthly), making automation a priority. Automated reporting can include:

- Number of consignees notified of the recall, and date and method of notification;
- Number of consignees responding to the recall communication and quantity of products on hand at the time it was received;
- Number of consignees that did not respond;
- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for;
- Number and results of effectiveness checks that were made; and
- Estimated timeframes for completion of the recall.

When using a dedicated recall response CRM database, this information is available to view and download quickly, whenever the authorities require it.

Proactively Partner with an Expert

Because food recalls are often complex, many manufacturers are proactively partnering with recall management experts to help them prepare for the unexpected occurrence of a recall or a crisis. This can have the most dramatic effect on the performance of any recall, as an expert can help in the following areas.

Determining responsibilities. Define terms and assign roles and responsibilities. Managers from across the company will be available to handle operations, production, purchasing, customer service, marketing, and finance.

Developing an online recall flowchart. This becomes the core ingredient of every aspect of recall management.

Messaging. Prepare a variety of messages for each recall class and divide them according to customer, stakeholders, and media. Have templates on hand with a choice of messages, which can easily be modified in a crisis.

Identifying the product locations. It's the company's responsibility to know the quantities in production, distribution, and which consumers have them and where they are. This links back to a recall CRM database, and is without doubt, the number one cause of recall announcement delays.

Notifying all affected parties. During a recall, it's important to follow the appropriate regulatory agencies' procedures in a timely manner, typically in this order: agency, distribution chain, and then consumer.

Commencing the recall and monitoring its stages. This includes:

- Remove: All efforts made to remove the product from the marketplace;
- Control: Ensuring recalled products do not re-enter the market;
- Dispose: Follow agency or other protocols for disposing of the item;
- Measure recall effectiveness: Check all appropriate actions have been taken and all parties notified, and whether consumer feedback is neutral, negative, or positive; and
- Recall termination: Only once all regulatory parties have authorized it.

Conducting and practicing mock recalls on a quarterly basis. This includes:

- Choosing a product for the mock recall;
- Traceing the product from the source to the finished product;
- Verifying communication systems, i.e., emails, address, telephone numbers; and
- Documenting each mock recall and modifying the strategy to correct any aspects not factored in.

Preparation is key in recall management, which hasn't changed in the digital age. However, digital tools help managers respond quicker, limiting brand damage. Still, for many companies, managing a major food recall is now too big a task and the risk too great to tackle it alone. Food recalls come with real costs that can damage the bottom line and destroy a brand. Investing in a partner that can properly manage a recall can often save a company millions of dollars in lost sales and reputational damage.

Remember that all crisis communication strategies should be revised on a regular basis. By ensuring you have digital channel experts in place as part of your crisis management team, your company is already in a good position to defuse any potential damaging situations. ■

Gillett is CEO of Marketpoint Recall, an international recall response agency. Reach him at pgillett@Mktpoint.com.

FDA's Recall Process Needs Improvement

The Department of Health and Human Services' Office of Inspector General (OIG) recently released a report to determine whether FDA is fulfilling its responsibility in safeguarding the nation's food supply now that it has mandatory recall authority. The report found that FDA did not always have an efficient and effective food-recall process that ensured food safety. OIG identified deficiencies in FDA's oversight of recall initiation, monitoring of recalls, and the recall information captured and maintained in FDA's electronic recall data system, the Recall Enterprise System (RES). OIG found that FDA could not always ensure that firms initiated recalls promptly and that FDA did not always: evaluate health hazards in a timely manner; issue audit check assignments at the appropriate level; complete audit checks in accordance with its procedures; collect timely and complete status reports from firms that have issued recalls; track key recall data in the RES; and maintain accurate recall data in the RES. For copies of the complete report, contact Public.Affairs@oig.hhs.gov.—*FQ&S*

Are Your Disposable Gloves Food Safe?

A scientific focus at why disposable gloves can amplify safety risks and how these can be mitigated with the type of glove used | BY **STEVE ARDAGH** AND **LYNDA RONALDSON, BSC**

The FDA Food Safety Modernization Act (FSMA) was introduced in 2011, aiming to prevent food contamination and subsequent foodborne illnesses rather than just respond to it. One overlooked element within the FSMA is disposable gloves. Labeled as intermittent contact items, the risk of contamination from these products is not seen as great enough to warrant close observation.

However, growing scientific evidence shows disposable gloves, in direct contact with food, can and do affect food safety, with around 15 percent of food service foodborne outbreaks implicating contaminated gloves as contributory factors in the outbreak.

What are Food Service Gloves?

Food service gloves are certified under FDA Title 21 CFR Part 177, which states that the components of the glove must comply with the FDA regulations and consist of "Substances generally recognized as safe for use in food or food packaging."

However, the quality and safety of disposable gloves is limited to Letters of Compliance and Guarantee on the general make and model of the glove submitted (once) for testing, not necessarily the subsequent gloves produced. There are few controls required for glove manufacturing relating to the reliability of raw materials, manufacturing processes, and factory compliance after the certification has been awarded.

It is possible for a glove manufacturer to achieve FDA Title 21 CFR Part 177 certification for a glove, then alter manufacturing and hygiene practices, and use cheap raw materials to save costs. Cheap raw materials lower glove strength, flexibility, and durability—increasing glove failure rates, and may also introduce toxic compounds, including known endocrine disruptors and potassium cyanide to glove users and food products.

Fluctuations in raw material prices and the demand for lower costs from the end user puts manufacturers under pressure to sacrifice ingredient quality and substitute raw materials to meet these demands.

The opportunity also exists for deliberate or accidental contamination within the manufacturing process, which the FSMA is now addressing.

Are Food Service Gloves Food Safe?

The AQL of a disposable glove is the "Acceptable Quality Level" and refers to a quality standard for measuring pinhole defects. Glove manufacturers test a random sample of gloves from a batch during initial production. The lower the AQL, the less defects gloves have. An AQL of 1.5, for example, requires that gloves be manufactured with no more than 15 failures for every 1,000 gloves produced.

In comparison to medical or examination grade gloves, no formal government regulations or inspection program exists for food service gloves over and above the FDA Title 21 CFR Part 177 regulation. There is no AQL requirement for food service gloves, meaning there are no guidelines for maximum pinhole defects—no guidelines for the number of failures per box.

Glove Holes and Contamination

Moreover, the human skin is a rich environment for microbes consisting of around 1,000 species, and the skin surface can contain on average 2 million to 10 million microorganisms. Most are resident species, some with the potential to cause disease (*Staphylococcus spp.* or

Streptococcus spp.), but transient pathogens are the driver of foodborne infection transmission.

Organisms can become resident colonizers on hands, and combined with a glove puncture, a "liquid bridge" of microbial contamination can flow to contact surfaces of food.

Studies have shown up to 18,000 staphylococci can pass through a single glove hole during a 20-minute period, even though the hands had been scrubbed for 10 minutes prior to gloving. With more than 250 different foodborne diseases associated with food or drink, there is ample opportunity for leaky gloves to share responsibility for transmission.

> There is no AQL requirement for food service gloves, meaning there are no guidelines for maximum pinhole defects—no guidelines for the number of failures per box.

In-use glove studies show that 50-96 percent of glove punctures go undetected by wearers, with the potential to release tens of thousands of bacteria from internal glove surfaces to food.

Chemicals that Cause Cancer

Vinyl (PVC, polyvinyl chloride) gloves are the most commonly used glove in food handling and processing in the U.S. due to assumed price savings. Up to 50 percent of vinyl glove raw materials are made up of plasticizers which, to reduce costs, can contain inexpensive phthalates DINP (Diisononyl phthalate) and DEHP (Bis(2-ethylhexyl) phthalate), and BPA (Bisphenol A).

Phthalates have been shown to leach from products into the human body via ingestion, inhalation, and dermal absorption. Because phthalate plasticizers are not chemically bound to PVC, they can easily leach and evaporate into food, particularly fatty foods, such as butter, oils, and meat—where they become mostly soluble. Phthalate plasticizers can also be absorbed through workers' skin and quickly contaminate food products.

Exposure to DEHP has been associated with adverse reproductive, neurobehavioral, and respiratory outcomes in children and metabolic disease risk factors such as insulin resistance in adolescents and adults.

Both DINP and DEHP have been found to adversely impact human health and have been added to the Californian Proposition 65 list of chemicals known to the state of California to cause cancer.

Studies conducted in Japan found that use of disposable PVC gloves during the preparation and packaging of meals was a major source of dietary intake of DEHP. The

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same study also demonstrated a decline in DEHP levels in prepared meals after the ban of DEHP in PVC gloves in Japan.

Food is likely contaminated with phthalates and BPA during processing from PVC in materials such as PVC (vinyl) gloves and food packaging materials.

In 2001, Japan banned PVC gloves for food handling due to the well-documented adverse effects on health. The European Union has banned the use of DEHP in food service gloves out of concern that the chemical will leach into food and be ingested.

Adverse health effects of exposure to BPA and phthalates in U.S. food and occupational settings is estimated to result in $175 billion in healthcare costs.

Vinyl Gloves and Cross-Contamination

Gloves have the potential to mitigate, transfer, or amplify cross-contamination risks.

There is a growing accumulation of scientific evidence showing vinyl gloves (over other types) are responsible for a majority of cross-contamination events in food handling related to glove use where glove type is identified.

Due to their polymeric structure, numerous studies have shown vinyl gloves have an increased permeability to bacteria and virus, and in some cases, begin leaking as soon as they are donned, increasing the risk of cross-contamination for both the glove users and the food they are handling.

Recent independent research conducted by international scientific consultant on food safety and glove expert Barry Michaels has also shown that the risk of cross-contamination via vinyl gloves when used in food handling is significant when compared to nitrile gloves.

The science involved in cross-contamination is complex, involving the physical chemistry of surfaces, soils, and pathogens. Liquid and soil transfer to and from surfaces is controlled by forces of attraction governed by the surface tension of liquids (or semi-solids) and the surface free energy of surfaces.

The surfaces of polyvinyl chloride (vinyl) gloves are more energetic than nitrile gloves, with pickup and spread thermodynamically favored. This means that food and human soil contaminants are more easily picked-up and spread over vinyl glove surfaces and anything they touch when compared to lower-stick nitrile gloves.

Published studies by independent investigators confirm that glove material and glove hydrophobicity were the most important factors influencing bacterial transfer from a contaminated surface to a gloved hand—more hydrophilic vinyl gloves favor transfer while the more hydrophobic nitrile gloves have reduced risk.

From a food safety point of view, because food worker's gloves are in direct contact with food, cross-contamination will follow the path of least resistance, in this case favoring vinyl glove pickup and transfer. Protecting food from bacterial and viral transfer from a gloved hand is essential for food and consumer safety to reduce foodborne illness and death.

As a result of his work Michaels commented that, "Food safety managers are gambling with the odds of a *Listeria monocytogenes* outbreak or some other extreme event, if they do not look at the science involving bacterial transfer and glove use. Conditions for cross-contamination can be disrupted by making scientifically based, food safe glove selection choices"

Consider the following takeaways when procuring your disposable gloves to lower the risk of adverse food-borne events.

- Only choose disposable gloves with an AQL of 2.5 or less—pay for gloves that are suitable for food handling. The cost of an inferior glove is low, but failure rates can be high.
- Beware of cheap imports that may be reject clearance lines—you may be paying for glove failures and the potential spread of bacteria and virus.
- Prevent glove fraud by purchasing from reputable suppliers with quality control procedures in place and known raw material content of gloves.
- Purchase cost-effective nitrile gloves to reduce the risk of cross-contamination of food.
- Following correct hand hygiene is essential. Effective hand washing procedures, including washing around and under fingernails, limit microbes exposed to the damp inner glove environment. ■

Ardagh is CEO and founder for Eagle Protect PBC, which specializes in the supply of food safe disposable gloves and clothing, while **Ronaldson** is VP of marketing at the organization. Reach Ronaldson at Lynda@eagleprotect.com.

For supportive literature on this article, go to the online version at www.FoodQualityandSafety.com in the February/March 2018 issue.

Further Instilling Good Personal Hygiene

BY **HENRY CARSBERG**

Gloves provide a barrier from bare hands, but disposable gloves have a one-time use. Case in point, in the medical field, gloves are used and changed as per patient. Likewise, when employees leave the food processing area, gloves must be removed; upon return, they must put on new gloves.

When preparing RTE or other food products in a deli, gloves must also be changed when the employee is moving from one product to another. For instance, shellfish to fin fish and fresh water seafood to salt water seafood. When I conducted sanitation training for a national supermarket's deli department, I noticed a food server who moved from cheese to sliced meats, then to macaroni salad and to deep-fried tenders, and finally to handling the money—all without changing their gloves. Unfortunately, this is not unusual. But it is wrong!

Gloves can provide a false hope if not used correctly.

As a result, I recommend using a liquid hand dip. Employees dip their bare hands in a solution of sanitizer, then they dry their hands. Similar to using gloves, employees need to be properly trained on using this system. Management needs to regularly monitor for compliance.

There are also hand sanitizing machines on the market that wash employees' hands in a warm sanitation solution and automatically dry their hands. I've found that most food employees prefer this convenient method. Any method that will encourage employees to sanitize their hands is a win-win situation. ■

Carsberg is a sanitarian with more than 30 years of experience in food plant sanitation. Reach him at henrycarsberg@yahoo.com.

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Quality

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Being Proactive About Grain Quality

Understanding the quality of their grain allows farmers to set a fair price and better negotiate with buyers across the country | BY **BRENNAN TURNER**

In recent years, sharp downturns in global corn and wheat prices have forced farmers to re-evaluate their grain marketing strategy. While hundreds of factors have impacted grain prices over the last decade, the ones that generate headlines typically center on broader macroeconomic issues. Two primary factors include: 1) the surge in corn production from Brazil and Argentina, which has increased competitiveness for American farmers, and 2) the rise of wheat production and exports along the Black Sea, which has created new price challenges for producers in the U.S. and Canada.

Naturally, shifting dynamics have driven conversations on grain quality at the local level. High-quality grains that meet rigid buyer specifications can capture a higher price. Most farmers know that higher protein content and less crop damage provides the opportunity to fetch a better price. For farmers to get ahead in the midst of continued grain pricing fluctuations, they need to address buyer concerns and incorporate several small, measurable steps into their best practices.

Global Reputations Start at Home

Most farmers already know where their crops are heading, who their buyer is, and what products will be developed from their harvest. But to understand the food quality challenges, they need to look at the broadest possible supply chain to recognize the impact that a few small mistakes can have on end products around the world.

The U.S. Grain Council (USGC) is responsible for marketing U.S. grain to countries all around the globe. Price and quality remain the two primary factors on which deals are based. In a low-price world, the organization has heard more and more about the importance of grain quality.

Tom Sleight, president and CEO of USGC, recently penned an editorial in which he explained how more buyers have increased their complaints about grains arriving on their soil. The list of complaints ranges from broken kernels and dust, to a diverse roster of foreign materials. This might seem like a standard concern, until you dig deeper and learn that the foreign materials include anything from stainless steel bolts and dead animals, to the "occasional" cell phone. These foreign materials did not magically appear at the final destination, and buyers have grown increasingly frustrated by the problem enough to seek alternative sources of grain.

"These concerns can affect our competitive position," Sleight wrote on the impact of these concerns. "In this marketplace, many customers look at all options—from South America and the Black Sea region."

Not all of these quality concerns are the direct result of farming operations, many are the result of multiple transfers into different vessels across a dozen time zones. However, it is important to know that whether you are 10 miles from a mill or the first stop of a trip into another hemisphere, food quality control starts at the farm level.

As the USGC explains, farmers can take a few steps to preserve grain quality. These factors can also play a major role in securing a higher price when they bring their grain to market.

Protecting and Preserving Grain Quality

Ensuring grain quality does not need to be a grueling task. Once harvest is complete, four simple steps can protect and preserve grain for when it is time to bring it to market.

1. Understand speed of harvest. In a conversation with Kurt Shultz, director of global strategies, USGC, he says that farm-

ers don't have a lot of control over events ahead of the harvest. Weather and other key factors can alter the pace and success of the harvest on a year-to-year basis.

However, the speed of the harvest can certainly affect the quality of the grain as it is gathered. Farmers rushing to gather their grain can increase the accumulation of foreign materials. Shultz says that this begins a chain reaction that leads to the accumulation of foreign materials downstream like dust.

2. Clean the grain and grain storage. Grain sanitation during harvest is the first line of defense against quality problems down the supply chain. Pests do not traditionally invade when crops first arrive in storage. They tend to enter bin openings or have been present in bins before arrival. Thus, sweeping a bin out before new grain is dumped into it is a simple way to manage against insects in the grain.

Another simple thing to do is get the grain tested to understand what good and bad variables are in the grain. The fact is, diseases like aflatoxin in corn or vomitoxin in cereals can cause serious problems for animals who are consuming the grain, and diseases can transfer up through the food value chain towards the consumer.

As all grain companies are now testing for these diseases, farmers need to be more proactive about knowing their grain's quality. This empowers a farmer to clean and/or separate good grain from bad grain, and ensures a higher quality food chain.

3. Focus on the drying process. Drying grain immediately after it is harvested is also critical as high moisture can create major quality problems. Spoilage and loss due to mold can begin to reduce the quality of grains in less than 24 hours. Farmers are better equipped to dry grains today than they have been at almost any time in the last several decades. Still, drying grain is a time consuming task, and proper drying techniques must be taken into account: utilizing appropriate heat, having correct levels of static air pressure in the drying chamber, cooling grains at a slow rate, and handling wet grains as little and as gently as possible.

Drying grain slowly prevents stress cracks in kernels, a problem that can compound. In fact, buyers from South Korea and Japan have recently raised concerns about dust once they reach the destination abroad, a direct result of cracked kernels in storage. Many farms have invested in chain conveyors or rubber belt conveyors in lieu of the traditional screw-type auger for moving grains. Despite the higher cost of such equipment over augers, the damage done to kernels is far less, and farmers may be rewarded for improved grain quality.

4. Monitor the grain in storage. As farm storage bins have grown in size, the task of monitoring the grain in the bin has become more difficult. Four decades ago, large farm bins were 10,000 bushels in size; today they exceed 100,000 in some cases. The expanding height and diameter of grain storage bins make detecting "hot spots" even more difficult than in the smaller bins of years past. Today, farmers often choose to invest thousands of dollars towards in-bin monitoring systems. These systems are sophisticated such that they detect changes in stored grain's temperature, humidity and moisture content, and the amount of carbon dioxide in grain bins. Farmers who detect spoilage quickly are often able to "rescue" a grain bin and prevent significant economic loss.

Getting the Best Price for Your Grain

The four processes listed above are critical steps for preservation and delivery of quality. But there is an additional step to the process that can ensure success and improve a farmer's reputation for quality. For farmers to compete on quality, they need to know what separates their grain from local competitors.

Farmers can take two important steps to ensure that they find buyers who are willing to pay more for their grain.

First, farmers should always have specifications on hand to ensure that they can begin the marketing process with all the information needed to attract buyers. Tight markets like the ones witnessed in the Summer of 2017 in the Dakotas had a shortage of high-quality wheat. With that in mind, many buyers scrambled to find higher protein levels to meet their quotas. Buyers are willing to pay more money for grain with distinct specifications like protein content, falling number and hard vitreous and non-vitreous kernels, and moisture levels.

In today's agricultural markets, low prices do favor buyers and reduce a seller's power. However, grain testing gives farmers more power in the market. For example, tools like FarmLead's GrainTests.com platform give farmers the ability to understand their quality by connecting them to over 50 independent grain testing labs to test their grain.

When buyers are stretched for product, they cite the importance of having all of the data in front of them to make a quick and sensible purchasing decision. "As a buyer, one of the most valuable things that we need to see is those tests," said Courtney Boryski, a grain trader with Hansen-Mueller, in an interview with FarmLead. "With durum, spring wheat, and hard wheat, we need to see these quality specs." Boryski admitted that she will pay more money for grain and related specifications that she needs.

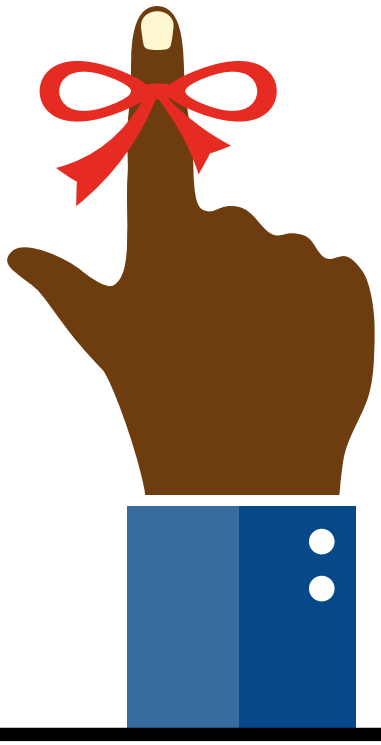
However, she also stressed the importance of having all of this data available. "It's valuable to see if they have grading tests for what they are selling," she added. "I may pay a higher price because I can get what I want."

The second way to get a better price in this environment is to consider alternative markets. One of the increasingly popular ways to meet new buyers is to engage them on digital marketplaces that enable farmers to showcase their grain and quality. Farmers who market their grain to more buyers have more opportunities to sell their product to new markets. In some cases, farmers who sell grain through online marketplaces are able to negotiate better crop prices than their local-market average. With access to more buyers, competition for high-quality products increase. In addition, buyers are able to quickly file through a number of offers and new sources that they may not have known existed in specific markets.

Adding a few best practices to farm management and grain marketing efforts will help farmers get a better price and improve their reputation for quality in an increasingly competitive industry. After all, the farmer is catering to the consumer. Getting the most of every dollar that a consumer spends on food is rooted in knowing the quality of grain as soon as it comes off the field. ■

Turner is the CEO of FarmLead. Reach him at b.turner@farmlead.com.

Reminder Why Audits Are Part of the Food Safety System



The benefits of having a certification system like SQF to meet customers' needs

BY **ROB CARPER**

Are you a believer in the benefits of having a documented and effective food safety system? Many food plant operators have built a system because most of their customers indicated that they would need to develop that system to continue doing business with them. As a result, a large segment of the industry has charged forward with Safe Quality Foods (SQF) and other Global Food Safety Initiative (GFSI) third-party certification systems to meet customers' needs. With many food production facilities now having SQF-like systems in place, it's a good time to explore the benefits of having this type of system.

Management Commitment

The strength of any food safety system is the commitment of management. This commitment drives a cultural shift at the establishment and is a requirement for any food safety system to succeed. SQF has inserted management commitment as the first requirement. When going the certification route, senior management is required to assign an "SQF Practitioner" to manage the food safety system.

The SQF Practitioner is like the system's "doctor" and maintains the commitment to safety with direct oversight for the food safety system through annual reviews and continuous improvement. In the past, Hazard Analysis and Critical Control Point (HACCP) food systems *recommended* management commitment in the guidance document, but SQF *mandates* it. If the practitioner practices the program and improves its structure and function over time, consumers will get products with higher and higher levels of confidence in food safety.

Constant review by this master of the system is required. Even though this is a requirement that is a benefit to the operation, practitioners vary in its use. If they have a strong process for review in place, it not only serves the customers and consumers, it can lead to improvements that reduce liability risk and save the company money through efficient operation and other discovered improvements. The requirements to be continually trained and to develop valid food safety plans also adds strength to the development of standards.

The Power of Certification

Getting an initial certification only means that the system meets the requirements of the standard in that moment. However, the ongoing implementation and maintenance of the food safety systems against the standards coupled with the annual independent audit requirement means food safety attributes and quality standards of the products are continually monitored and improved.

Many businesses seeking certification thought that once they were certified, they would be "Compliant" forever as long as they did not change a thing. Unfortunately, this strategy did not apply to the "modern" GFSI-recognized schemes. These were designed to be under constant review and improvement. Since 2008, the SQF standard has undergone five revisions (Editions 6, 7.0, 7.1, 7.2, and 8.0). The SQF Technical Review Committee is responsible for making updates to the SQF Code and is comprised of stakeholders with representation from food retailers, certification bodies, and food processing professionals with experience and insight into how to construct effective food safety programs. This periodic revision process has forced SQF Practitioners and the industry to embrace and manage their food safety systems in a manner that manages change and constantly improves their food safety systems to adapt to these changes. As an example, the SQF Code requires that all SQF-certified food processors (called "suppliers" prior to Version 8.0 but now called "sites") comply with existing government food safety requirements. Ultimately senior management is kept informed as to how the system is delivering safe food and protecting their brand and the consumer.

The Power of Audits

Another important attribute to GFSI-recognized schemes, such as the SQF standard, is that there are rigorous criteria and ongoing training requirements to become a licensed or certified auditor. All auditors within these systems must have prior knowledge, education, and experience in a specific food sector. Again, the strength and value of the audit is dependent upon the thoroughness and professional capability of the auditor. The auditor is required to re-register each year to confirm that they continue to meet their requirements for registration. One weakness that is appearing in the GFSI-recognized systems is the lack of any requirement to conduct field evaluations of auditor performance, which

has been demonstrated to be an issue in a few instances where FDA has conducted investigations soon after a GFSI third-party certification audit and the differences in the finds was significant.

The frequency of the audit is also important as well as whether it is "announced," allowing the plant to prepare, or "unannounced," allowing the auditor to get a good idea of the day-to-day operational norms in a food processing plant. Annual audits are required by most of the GFSI-recognized third-party certification schemes, including SQF. A new feature in recent years has been the addition of *mandatory* unannounced SQF audits of all suppliers a minimum of once in every three-year audit cycle.

With all GFSI third-party certification programs like SQF, the Certification Body (CB) audits the food processor ("site" in SQF vocabulary) and in turn, is audited by the American National Standards Institute who reports the outcome to SQFI to make sure CBs are applying the SQF standard correctly. The site requesting certification is re-audited each year by a registered SQF auditor qualified to audit that particular type of food. These site audits are required each year in order to maintain a supplier's SQF certification. This provides a true "third-party" component.

Companies preparing for an auditor's visit often choose to have a pre-audit conducted with an independent third-party who will come into the facility with the same fine-tooth comb, looking for where food safety systems are running well and where they can be improved.

Annual audits are a "good" thing because they protect the company and the consumer by ensuring the products are manufactured using adequate:

- Food Safety Fundamentals (prerequisite programs and other requirements);
- Food Safety Plans, such as HACCP; and
- Quality Plans (a requirement for SQF Level 3 certification).

Food safety plans must be monitored and verified throughout the year, making sure the entire written food safety program is being supported with detailed records at the right frequency, capturing operational data. All food safety criteria are required to be supported by records, or it did not happen. Each record must be signed by the plant person conducting the activity and verified by a trained supervisor or other authorized individual. Effective audits and auditors have to make decisions about which records and how many records need to be reviewed as part of their audit plan to provide confidence that the plant was and is implementing its food safety plan in an effective manner.

Within the SQF system, the SQF Practitioner must conduct verification and validation checks of the entire SQF food safety program, identify any gaps, and establish a corrective action plan to fix these gaps. This could be done using internal audits, analysis of processing data using statistical process control, trend analysis, ingredient and finished product testing, or some other metric that would indicate adequate implementation on a day-to-day basis or maintenance of safety/quality.

Without regular external and internal audits, the commitment of the organization and the status of the food safety system would be in question and eventually the diligence in maintaining the system would suffer. In other words, with competing interests, it is conceivable that food safety could fall from the highest priority level list with these resources reallocated, if audits did not occur.

While no system is perfect, consistent annual auditing enables most operations to achieve "good" or "excellent" within the current SQF or their own internal rating system. Although perfection is probably not obtainable, excellence is certainly a goal. Experience has shown that if senior management reinforces the need to achieve "excellence," then it becomes an organizational goal and is obtainable. The audit does keep the system alive and improving, whatever level is achieved.

Customer Expectations Are Met

The customers (buyers) expect excellence in food safety systems, whether the site has achieved a GFSI-based third-party certification, such as SQF, or by other means and recognized systems. The main goal is to demonstrate a safe and high-quality product for their customer (at retail or food service level). In most cases, buyers have come to expect certification in order to accept food products from suppliers/sites, but whether choosing to go the GFSI route or not, senior site managers should be allocating enough resources to reaffirm their food safety commitment annually.

A well-managed food processing plant with an effective food safety system utilizes the skills of its food safety personnel as well as organizational tools such as internal and external audits. All staff are held accountable, ensuring that the food safety team is operating properly, customer complaints have been addressed, and improvements have occurred. ■

Carper, who has been in the food safety business since 1975 when he was a veterinary specialist in the Air Force, is currently an independent consultant at EAS Consulting Group, LLC. Reach him at rcarper@easconsultinggroup.com.

Are You Ready for Your BRC Audit?

Taking a close look at the fundamental requirements in BRC to help with certification/recertification

BY **CHARLES GIAMBRONE, MS**

After 25 years of existence, the British Retail Consortium (BRC) still retains a dominant role in U.K. and Europe with 65 percent of registered sites, and 11 percent in North America, according to BRC Global Standards Compliance Program 2016. Although the BRC food safety standard began in the U.K., it is now recognized as a global standard in the Global Food Safety Initiative (GFSI) benchmarked scheme.

The current version of BRC is Issue 7, which began officially in July 2015. There are several key modifications/changes for BRC Issue 7 versus Issue 6. Audit protocol's scopes and exclusions have been tightened to reduce exclusions to an audit. Excluded products must be manufactured in a segregated area of the facility. Supplier approval is another addition to create a convergence with the U.S. FDA Food Safety Modernization Act requirements under its Foreign Supplier Verification Program.

Also in Issue 7, high-risk suppliers must have more stringent verification than simply using questionnaires or certificates of analysis. The objective is to have the supplier adhere to a certification in a recognized GFSI scheme, plus take part in first- or third-party audits.

Labeling and packaging control have also been tightened in Issue 7, with a required formalized process in label changes and verification. Another key change is that a BRC certified site must have a documented system to authenticate a facility's supply chain. A risk assessment program must be performed on all raw material types to assess adulteration of each specific raw material. This needs to be kept updated and current to show dynamic market changes.

BRC has conducted unannounced audits as part of its scheme for some time. If you decide to opt for the unannounced audit scheme you have to notify your certification body within three months of your last audit date. You then have to decide which option to pursue: Option 1 (full unannounced) versus Option 2 (two-part unannounced audit). Option 2 breaks it down focusing on Good Manufacturing Practices (GMPs) in Part 1. Once corrective actions are completed and verified within a 28-day period, then Part 2 is undertaken, which focuses on systems and documentation. Part 2 can transpire within a 28-day window. My perspective as a former QA manager is that I would opt for Option 1 to get the process done in one full chunk of time. However, I can understand why certain plant operations would opt to truncate the process using Option 2.

Fundamental Requirements

The following are several fundamental requirements that involve actual food safety plant issues that I have directly dealt with in my career. However, please keep in mind that all requirements in BRC are critical to your program's success.

Senior management commitment and continual improvement. Reviewing programs of my GFSI customers, I find the most disconcerting aspect is the "Groundhog Day" syndrome, namely the same issues or problems are not resolved and are continually reoccurring.

The utilization of Band-Aid remedies are criticized by GFSI and BRC. If non-conformities are repetitive or are resolved without ascertaining "root cause analyses" of non-conformities, the Band-Aid corrective actions do not comply with the ethos of BRC. Specifically, Part 1 Clause 1.1.10 states clearly that senior management "shall ensure that the root causes...have been effectively addressed to prevent reoccurrence." So, if an auditor finds the same issues being quickly remedied to pass an audit, that in itself is a significant red flag.

Food safety plan review and reassessment. Both the Hazard Analysis and Critical Control Point (HACCP) plans and prerequisite programs (PRPs) must be reviewed, adjusted, and updated prior to the announced or unannounced audit. HACCP plans and PRPs ought to be living, dynamic documents that are continually reviewed, fine-tuned/tweaked, or overhauled depending upon changes in personnel, operations, product portfolio, regulations, and equipment, to name a few.

Review and reassessment CPs and CCPs must be done on a consistent basis by the entire HACCP team, and not just the quality team.

Internal audits and corrective and preventive actions. Audit teams should include cross functional groups and no audit team members should audit their own work. The internal audit teams must have consistent ongoing refresher training since BRC is a living, dynamic program.

All listed non-conformities should be resolved through corrective actions via root cause analysis to truly attain

continuous improvement. The need to assess and correct food safety failures is critical. Remember no Band-Aids here. By documenting the non-conformities, establishing clear reasonable timescales for correction, and using root cause analysis to prevent recurrence, you can create bonafide continual improvement in your food safety program.

Layout, product flow, and segregation. In most instances for new state-of-the-art facilities, product flow and segregation in the facility design are done well. But in many older plants, this fundamental requirement is a major concern that needs significant capital improvements and creativity to achieve proper plant design and prevent cross-contamination due to flawed product flow and poor segregation of the raw to finished side of plant operations.

Any plant manufacturing RTE or RTU products must be diligent in mapping low- and high-risk zones with high-care and high-risk areas being the critical focus. The site maps have to clearly outline doors for forklifts, pallet trucks, and people while mapping typical traffic routes as well. This includes traffic flow of finished product, in-process products, and waste products.

Be sure to properly plan the mapping before the capital expenditures and construction are undertaken to eliminate the root cause of cross-contamination due to poor layout design and segregation. Issue 7's Appendix 2: Guideline on Defining Production Risk Zones is a "must" read and should be annually reviewed roughly six months prior to BRC certification.

Training and allergens. For the permanent employee, continual cross-training is mandatory. An employee performing a critical operation must understand the whole production process and appreciate the HACCP plan and PRPs for their current or future job functions. The re-training must challenge the employee and re-address, in a new perspective, key precepts of the plant's operation, basics of food safety, PRPs, and cGMPs. Plant personnel must understand and be able to explain the "why" as well as the "how to."

Having food safety cross-training enables the plant team member in question to be more valuable to the organization by providing the operation with a degree of flexibility. This includes the sanitation team, a key cog to the performance of a plant's BRC Standard and HACCP program. An ideal training tool for production personnel and sanitation staff is to have a hands-on class reviewing a SSOP with either a problematic piece of equipment or environmental sanitation niche (i.e. drains).

And lastly, many BRC certification sites generate non-conformities due to allergen mislabeling, allergen raw material storage, and allergen changeovers on production lines. Equipment and environmental sanitation procedures must be continually reviewed to ensure safety when a production line goes from one type of allergen to another or to a non-allergen product. ■

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In The Lab

MOISTURE

Heat-Treated Flour Validation

Using dry surrogates as the basis for a gold-standard validation in low-moisture foods

BY **BRIAN UMBERSON** AND **JENA ROBERTS**

Many of us have had to resist the urge to lick the bowl of the brownie mix or sneak a bite of cookie dough but many don't resist the urge. The growth of ready-to-eat (RTE) flour can be traced to multiple food safety recalls, most recently in 2016, when the FDA investigated a multistate outbreak of Shiga toxin-producing *E. coli* infections linked to large domestic producer of flour. The impetus for these recalls stems from consumers consuming a not-RTE product (flour) prior to the kill step. After months of extensive testing, the pathogens *E. coli* O121 and *E. coli* 026 were detected in laboratory samples.

The risk of foodborne pathogens is increasing in grain products. U.S. wheat production is concentrated in the Midwest where livestock and poultry operations are also important to the agricultural economy. Farms and wild animals serve as a reservoir for these pathogens and with such close proximity, *Salmonella* or *E. coli* can be introduced into wheat fields and thus into wheat operations.

In his recent newsletter article, David Acheson, MD, founder and CEO of The Acheson Group, noted that, "Flour has never been considered to be a ready-to-eat food. It is not treated as such in the field, in production, or at the consumer's home. But with the regular flow of recalls caused by consumer consumption of raw flour, that may be about to change." Dr. Acheson adds, "Will this impact regulation? Very likely. Eventually. But at the speed that regulation flows, I would recommend that, for both consumer and brand protection, any company selling a raw product to consumers take steps to determine if it is cost effective to add a viable kill step that would not compromise the product, and look for other cost-effective ways to reduce the risk through supply chain and processing controls."

The grain products industry is adapting to environmental and consumer behavior induced risk. With a series of food illness outbreaks associated with low-water activity foods, the long-held belief that low-moisture foods are not a food safety risk is no longer valid in today's world. The need to protect consumers and the corporate brand from the increasing risk has created a need to treat flour with a process that applies a kill step as a preventive control for foodborne pathogens like *Salmonella* or *E. coli*.

Treated Flour and Pregelatinized Flour

Treated flour is the result of heat, stress, and shear to reduce the risk of foodborne pathogens. Treated flour is used primarily as a RTE ingredient in products containing flour that might be consumed prior to cooking, such as cookie dough, ice-cream additives, mixes, seasoning blends, etc.

Pregelatinized flour serves a nutritional and process efficiency requirement that is also the result of heat, stress, and shear but not categorically enough to be considered a RTE product. The heat, stress, and shear required to create pregelatinized flours is very specific to break down the starch molecules with water and heat.

Pregelatinized flours perform well in cold water applications, thus enabling quicker mixing methods and they can gel without high heat. Pregelatinized flours can improve dough performance, increase viscosity, and suspend ingredients and are used in prepared and frozen products, sauces, many food preparations, baby foods, yeast products, ice cream, etc.

Treating Flour with Thermal Stress

Extrusion and radio frequency (RF) are examples of two processes used to further treat flour and provide a RTE ingredient.

By nature, extrusion is a continuous process where a food material is forced to flow through a die by a combination of mixing, shear force, and/or heat. A versatile technology with origins in the plastic industry, extrusion is a short-term, high-temperature process, used in a wide variety of products including flour, cereals, snacks, pasta, pet food, and livestock feed. When flour is heated by barrel heat,

internal friction, and plastic flows of the product, (if validated) this process can be a preventive control step.

With the Food Safety Modernization Act (FSMA), there is an unquenched desire for more diverse forms of pasteurization, and RF heat treatment is a growing method of pasteurization for dry food products. Recent advancements in RF have alleviated many of the hurdles associated with non-uniform heating of products. Current designs allow for deep penetration of heat and uniform heating to ensure food safety.

In RF heating, a generator creates an alternating electric field between two electrodes. RF waves penetrate the food product and create heat energy by either orientation polarization, where the electrodes cause the water molecules in the product to continuously reorient themselves to face the opposite electrode or by ionic conductivity, where hydrated ions move according to the electric field. In both cases, heat energy results in the rapid heating of the product. RF is a good candidate for either a bulk or bagged product.

Validating a Heat Treatment/ Kill-Step

FSMA Preventive Controls mandate that only process preventive controls must be validated; allergen, sanitation, recall, and supplier controls do not have to be validated. FSMA recognizes five approaches to validate a process preventive control measure. These approaches include: 1) reference to scientific or technical literature, previous validation studies, or historical knowledge of the performance of the control measures; 2) scientifically valid experimental data; 3) collection of data during operating conditions of food production; 4) mathematical modeling; and 5) surveys.

As a company evaluates these approaches, it may soon discover scientific and technical information is not available or is insufficient to support that the preventive control controls the hazard. The next step will be for the facility to conduct controlled scientific studies to establish that a preventive control measure is adequate to control the hazard.

While laboratory challenge studies are one way to conduct scientific studies, they can be fraught with inherent errors, the foremost being food processes are difficult to scale down to laboratory scale. Performing an in-plant, preventive control validation study is a gold standard approach to validation. What better way to validate a preventive control than with using the actual product and process.

In order to safely perform in-plant validation work, using surrogates is ideal. An appropriate surrogate is not a pathogen. It has a similar or greater thermal relationship when compared to the pathogen(s) of pertinence, it will not establish itself as a spoilage organism in the plant, it is easily killed during routine sanitation, and it is easy to detect and enumerate.

With the advent of dry surrogate technology, a smarter food safety tool has emerged for in-plant preventive control validation of low-water activity foods, including validation of hurdle technology or flour processing steps. Dry surrogate inoculation leads to minimal intrinsic property changes. With little to no intrinsic property changes, flour inoculated with a dry,

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Events

MARCH

6 - 8
Food Packaging Short Course
Penn State University
Visit http://agsci.psu.edu/food-packaging,
email CSCO@psu.edu,
or call 814-865-8301.

6 - 8
FSPCA Preventive Controls for Animal Food 2.5 Day Course
Twin Falls, Idaho
Visit www.techhelp.org/events/400/fspca-animal-food-2-5-day-course-twin-falls/,
email jenniferbuel@techhelp.org,
or call 208-426-3767.

26
Blended Preventive Controls Qualified Individual Training (Part 2)
Salinas, Calif.
Visit http://www2.unitedfresh.org/forms/meeting/MeetingFormPublic.

27
United Fresh Recall Ready Workshop
Salinas, Calif.
Visit http://www2.unitedfresh.org/forms/meeting/MeetingFormPublic,
email bmassoud@unitedfresh.org,
or call 202-303-3404.

APRIL

24 - 25
Dairy Plant Food Safety Workshop
Plymouth, Wis.
Visit www.usdairy.com/events,
email chad.galer@dairy.org,
or call 847-627-3249.

MAY

7 -10
Food Safety Summit
Rosemont, Ill.
Visit www.foodsafetysummit.com.

9 - 11
Global Food Contact 2018
Bethesda, Md.
Visit https://www.food-contact.com/global-food-contact,
email bnorton@smithers.com,
or call 330-762-7441.

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ready-to-use surrogate can be used immediately after inoculation without a lengthy time period to re-equilibrate to original %moisture or Aw. Inoculation with a dry surrogate is homogenous and eliminates product clumping seen when inoculating a dry powder with a liquid surrogate. The ability to produce large, stabilized volumes of dry surrogate means that large volumes of food product can be inoculated. There are times when thermal bags, which are product inoculated with surrogate and placed in thermally-resistant bags, are not appropriate for the process. Obviously thermal bags will not fit through an extrusion process, they often won't travel at the same speed as free-flowing product in a screw process or thermal bags may not experience the same thermal conditions as free-flowing product. With commercial production, high surrogate concentrations are also realized. While validation will not be performed at high concentrations, it does allow for inoculation of product with high background microflora with the ability to still evaluate for a 5-log lethality. The shelf life of dry surrogate has been evaluated to be at least three months when stored under refrigeration.

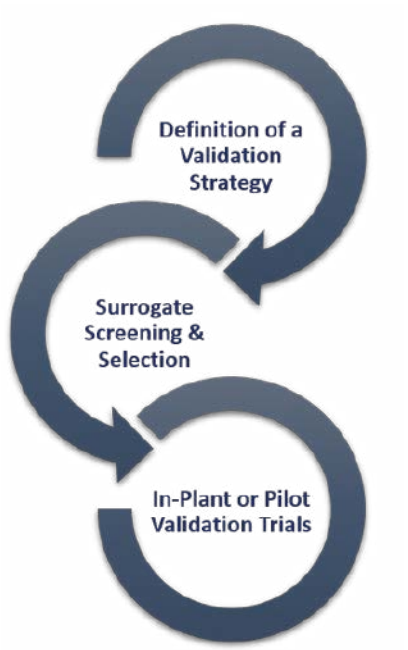
Validating Extrusion and RF

The advent of the new treated flours for better nutrition or commercial cooking is inherently tied to flour treatment for microbial content. Treated flour has a tight processing window regarding microbial lethality and nutrition modification of the grain by-product. The tight processing window for treated flour as well as consumer and brand liabilities require companies to fervently reduce risk with gold standard validations and periodic verification trials to insure calibration of the process.

As Dr. Acheson stated previously, manufacturers should, "...add a viable kill step that would not compromise the product, and look for other cost-effective ways to reduce the risk through supply chain and processing controls," so a plan to reduce risk should combine process validations and verifications to ensure a process is in control and within acceptable deviations of the process calibration.

A dry surrogate can easily inoculate small and large quantities of food. The dried

Validation Process



and ready-to-use surrogates are blended to create inoculation with flour. The blending can be a function of simply pouring the dry surrogate into the pre-conditioner (mixer) of an extruder, or distributed in thermal bags, or as a large volume inoculation of multiple tons of product. The thermal bags are an efficient method of distribution to confirm thermal penetrations by RF treatment in bulk capacity bags.

An in-plant validation project with surrogate microorganisms commonly includes three major steps and dry surrogates are no different. The first step is to define a validation strategy that is based upon the following.

- The level of inoculation for the surrogate organism, taking into account detection limits and background microflora of the tested product matrices.
- The inoculation method for the surrogate (liquid vs. dry vs. combined inoculation method).
- The product and in-plant process will dictate the distribution method for the surrogate. It may require a containment method with resistant bags. The dry surrogate enables bulk inoculation of large quantities that can be performed in a lab or at the plant.
- Transportation and storage guidelines.
- The number of validation trials to be performed (a standard industry practice is three validation trials).
- The placement and recovery of the surrogate in the process: number of samples to be tested, non-treated and control samples, required staff, etc.
- Target enumeration protocol (selective vs. non-selective vs. combination method, number of replicate enumerations, etc.).

The second step is to verify the resistance of the surrogate at lab scale, which is particularly important for data validity. A surrogate must demonstrate similar or greater thermal resistance when compared to the target pathogen to be considered effective. A food matrix can have significant effects on pathogen heat resistance during processing. The resistance data is more credible after developing:

- The number of surrogates to evaluate (usually one to three) and the choice of the surrogates to test;
- The inoculation methods and levels for the surrogate and the pathogen(s) to test (cocktail vs. single strain, dry vs. liquid form);
- The inactivation stress to be applied (dry heater apparatus, oil bath, lab oven, chemical bath, chemical spray, etc.);
- The processing parameters and exposure times to be evaluated; and
- The number of assays (two or three in general) and replicate enumerations.

The third and last step consists of performing validation trials directly on the kill step within the in-plant processing equipment. The product matrices will be inoculated with the surrogate and then distributed within the in-plant processing equipment. Post-process samples will be collected and analyzed, which can determine the capacity of the kill step process to inactivate pathogens.

Dry surrogate technology is uniquely capable for use in in-plant process preventive control validations to create "gold-standard" data to validate the process, which is a pivotal benefit for food safety and regulatory compliance.

Dry surrogates are great, but you still need to resist the urge to sneak a bite of raw cookie dough. ■

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NOVOLYZE

LIMS: Making Life in the Lab Much Easier

Using integrated informatics can translate to increased productivity and better management of complex global food safety regulations

BY **BARBARA VAN CANN**

In the same way that technology expands the reach of information on a global scale, it can aggregate information from various divisions within the same enterprise to create a portal for superior organization and business intelligence. Frequently, more than in other industries, the food business is under extreme pressure to ensure the production of quality products while maintaining strict regulatory compliance and a high level of productivity. Without adhering to these rigorous standards, companies run the risk of audits, recalls, erosion of consumer confidence, and loss of brand integrity.

Food producers and manufacturers need to go through a complex web of processes to bring raw materials through their production lifecycle to packaging and release to the market. With diverse remote sources involved and multiple divisions within each company, all procedures require meticulous monitoring and constant improvement to keep up with the high demands of the world's growing consumer base. In addition, global regulations require stringent controls, ensuring the food put on tables is safe for consumption. Implementing data management systems to monitor and collect a multitude of testing and quality control data allows these companies to focus on their primary objective—bringing safe and healthy food from farm to fork.

Data management systems have become the foundation of any food safety laboratory to track samples and comply with increasingly complex regulations, but how does implementing an integrated laboratory information management system (LIMS) help to increase productivity and streamline workflow without taking too much time dealing with the system itself? Here are some tips and best practices for working with LIMS, how to leverage the integrated system, and why it is essential for managing today's complex global food safety requirements.

Identify and Manage Fail Points

From a food safety and quality perspective, there are several potential fail points within a typical food manufacturing process that must be recognized and closely tracked. Monitoring these checks across multiple processes can quickly become overwhelming, causing delays and eventual bottlenecks in overall production. From receiving raw material to competent batch release, laboratories can have a substantial influence on production speed and efficiency.

In order to increase lab efficiency and not tie up man-hours in the tracking of every individual procedure, it is important to itemize all fail points, establish a protocol for these hazards in the LIMS, and manage processes so not even the smallest detail is left to chance. Integrated informatics builds in fail points in order to preserve data integrity across three common areas where prevention is key to success: inventory, standard operating procedures (SOPs), and traceability.

Inventory. Cataloging products can initially seem like a basic management project. Most laboratories run routine tests and regularly need the same stocks replenished. However, because inventory is generally a straightforward process, fail points regarding pre-planned ordering or automated supply level monitoring can easily be overlooked. Using a LIMS to electronically track supplies as they are used and send an alert when items are running low enables labs to maintain their efficiency and eliminate fail points in this area.

SOPs. These are one of the most significant procedural necessities in any lab, outlining what needs to be done and exactly how. Straying from SOPs can cause severely detrimental effects for food safety due to unintended errors that could be avoided. A LIMS can implement electronic SOPs to protect against this risk and statistical quality controls to detect non-conformance, defining stepwise workflows and technical corrective actions to ensure consistency and adherence to protocols.

Traceability. Tracking and logging a product from origin to release provides accountability and accuracy of results needed for quality control and regulatory review. Given that labs typically work with thousands of samples, this process can be laborious and full of potential fail points. Without a documented and unbroken chain between data and sample, results become indefensible. An integrated informatics solution reinforces adherence to encoded guidelines, safeguards data quality, and accelerates the delivery of results so that production can continue uninterrupted.

Maximize Process Improvement

Most quality assurance and quality control systems follow the Hazard Analysis and Critical Control Points (HACCP) methodology. HACCP aids in the development

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of relevant regulations to ensure proper workflow and prevent food safety hazards. In order to handle the extensive volume of instrument data and records generated from comprehensive HACCP programs, labs can leverage LIMS to collect and manage data over the entire lifecycle of a food product. Analysis of data from this approach aids in the improvement of involved processes by considering the five critical steps outlined below.

Hazard evaluation. Evaluation of potential hazards that can arise from user interaction, raw material handling, or packaging can bring to light process areas that need close monitoring or automated protocols. Allowing LIMS to manage these identified hazard points makes preventing issues simpler and managing the effects of process errors less consequential.

Preventive steps. Prevention is extremely important in eliminating potential hazards before they arise, removing the need to cope with hazard response. Users should define preventive measures and manage them with a LIMS, including automating instrument maintenance reminders, electronically updating user training documentation, or monitoring product quality checks for non-conforming products. Resulting process workflows will prevent potential issues that could severely impact product, site, and user safety.

Monitoring controls. Automatically establishing monitoring controls in a LIMS after inputting hazard points and preventive measures further simplifies monitoring tasks by scheduling measurements, setting alerts, applying control limits, and analyzing data in one integrated system for easy planning. All data generated from workflow monitoring can then be stored in the LIMS database for thorough review.

Record maintenance. Food safety regulations require extensive recordkeeping, which can result in piles of separate data trails. Integrating a LIMS to maintain monitoring records organizes data into clear and comprehensive archives, simplifying recordkeeping and offering easy retrieval for review.

Corrective actions. Specifying corrective actions in advance through a LIMS results in more effective decision-making by providing clearly defined resolution protocols in the event of an incident and decreases error response time. Once an issue has been resolved, the LIMS enables quick assessment of the extent of an issue for informed process improvement.

Automate Compliance Management

Food production is truly a global business and one that is scaling rapidly. Regulators have therefore introduced more standards in order to encompass global progression, and control the broad expansion of the food and beverage industries. Even stricter regulations from the U.S. FDA and the European Union (EU) have been affected and updated to accommodate this growth by focusing on audits that assess industry practices instead of acting after an adverse event. An integrated informatics platform provides access to large amounts of information in a timely manner, allowing food producers to provide proof that activities were performed properly, records collected precisely, and enable access to accurate supporting information.

Automating compliance management helps to guarantee processes and controls meet the strictest requirements. Voluntary standards such as ISO 22000 and mandatory regulations, including the U.S. Food Safety Modernization Act and the EU Regulation No. 178/2002, enforce the quality and safety of food products and provide clear benchmarks for accountability. Building in regulation parameters to a LIMS provides a systematic approach to ensuring compliance with multiple regulatory requirements across all networked facilities and through every step of every process.

Relying on a LIMS for automated compliance promotes higher quality processing and manages workflows to provide accurate data to auditors and reduce contamination risk. Through the management of all aspects of production, LIMS gives users insight into data capture necessary for regulatory reporting and control. This benefits food producers by increasing efficiency, improving product safety, and reducing or minimizing the impact of recalls. As a result, optimal production practices protect the brand by assuring food is safe from contaminants or impurities, thus preventing any instance of recall or harm to the public which could erode trust in the brand from consumers.

Create a Central Repository

A centralized database offers flexibility for users to correlate data and combine results for an overall depiction of the food production process. Collecting data from every workflow and monitoring control into one location with a LIMS ensures robust traceability, confident contamination and recall management, and solid data assimilation to verify regulatory compliance.

An integrated informatics system stores all information in a single platform, automatically recording and retaining system maps within the data records to describe relationships between batches and the connection between instruments, methods, specifications, and results. Managing lab activities in this way delivers more consistent and reliable data since it is being collected in the same way for all users.

Implementing a LIMS to centralize and manage test data facilitates end-to-end traceability of samples, products, and associated laboratory procedures. This increased traceability of products throughout their lifecycle allows companies to analyze process efficiency and adjust production to create improved processes, ultimately producing better products and easing regulatory reviews.

Be Adaptable

Implementing an enterprise-wide LIMS system offers versatility and improved time management capabilities so that users can efficiently perform tasks in addition to analyzing how procedures can be updated and improved. Integrated informatics solutions give food companies the tools to asses and review manufacturing productivity across the supply chain, while detailing each step in a process to investigate the quality and safety of work being done. By learning from the data provided by the LIMS and adapting processes to improve productivity, use of integrated informatics can translate to enhanced business intelligence while providing more innovation, powerful automation, and in-depth integration to accelerate informed decision-making and provide the opportunity for transformation and growth of the enterprise. ■

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Mastering Traceability Basics for Blockchain Success

Breaking down what blockchain is, how it can be used in future traceability processes, and the key steps a company needs to take before attempting to implement

BY **MELANIE NUCE**

Last summer, several major food manufacturers and retailers including Nestle, Unilever, Tyson, Walmart, and Kroger joined together to announce a major exploration of blockchain technology for food traceability. This announcement drew attention to blockchain as a technology that had real applicability for food safety and has helped the food industry envision the possibilities of blockchain beyond its cryptocurrency origins.

As more companies explore its possibilities, it has become clear that blockchain represents an opportunity to efficiently manage supply chain data across a complex network from farmers, to distributors, processors, retailers, regulators, and consumers. With the promise of amplifying traceability, blockchains record specific information about products as they move throughout the supply chain. Although industry analysts say blockchain is still very much in its infancy, now is the time for companies to educate themselves on its benefits and how it can lead to vast improvements in efficiency and security in the food supply chain.

Blockchain = Shared Database

Blockchain was first used in bitcoin—digital currency operating independently of a central bank. The blockchain technology that underpins bitcoin is proving to offer valuable benefits to use in cases outside of the financial world. Casting the catchy buzzword aside, blockchain at its core is a shared database. Many industry veterans already know that shared databases have benefits, but what makes blockchain special is that it is a distributed ledger. There is no single point of failure in a distributed ledger—it is a consensus of replicated, shared, and synchronized digital data geographically spread across multiple sites.

This decentralized structure makes the data resilient to a technology or organizational failure. This, in theory, could significantly change the way companies access and store important documents and transactional histories. For instance, in developing countries, where paper documents can be destroyed in a natural disaster, or electronic copies can be lost in unstable economic conditions, blockchain represents a huge opportunity for consistency.

For the past few years, technology providers like IBM and Microsoft have been focusing on taking blockchain from being a public ledger to an enterprise solution designed to solve supply chain problems. Enterprise blockchains are decentralized in nature, meaning there is no one central point to hack, and support multiple levels of permissions for robust security around who can write to and read from the ledger.

Standards as a Foundation for Blockchain Traceability

Driven by consumer demand for safer food, the global food traceability market is expected to grow to $16.09 billion by 2022, according to a report from Research and Markets. For several years, food suppliers, manufacturers, distributors, retailers, and technology providers have collaborated to enhance the retail grocery and food service industries' ability to trace products from farm to fork. Industry stakeholders participating in initiatives such as the Produce Traceability Initiative, the Foodservice GS1 US Standards Initiative, and the GS1 US Retail Grocery Initiative have made significant progress in moving traceability forward. While some have made more

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traceability progress than others, these more than 200 industry participants have at least committed to taking the first step toward the track and trace of products using GS1 Standards. Many have moved along to adopt other GS1 Standards for automated data capture through the use of standardized barcodes, and the ability to share data in real time through a continuously updated network of product data called the Global Data Synchronization Network. With all of these standards working together, a company can have supply chain visibility—a crucial first step that can set a company up to maximize blockchain's power in the future.

> Although industry analysts say blockchain is still very much in its infancy, now is the time for companies to educate themselves on its benefits and how it can lead to vast improvements in efficiency and security in the food supply chain.

GS1 Standards enable traceability by ensuring all trading partners communicate in a uniform manner. Standards ensure systems interoperability, and provide a singular approach to maintaining product information that supports, at the very least, "one up/one down" visibility of the product's movement through the distribution channel. The internal data and processes a company uses to track products is integrated into a larger system of external data exchange that takes place between trading partners.

Traceability has permeated the fresh foods industry to varying degrees. For example, more than 65 percent of the produce industry has implemented traceability based on GS1 Standards, motivated to erase negative consumer perceptions of the long and dangerous food recalls of the early 2000s. The meat industry has also been leveraging standards for product traceability for more than 20 years. By contrast, the seafood industry has just begun its traceability journey, as it works through challenges with how to identify product from the source. However, there has recently been an increase in the use of barcodes by distributors and retail outlets, which may drive the adoption of GS1 Standards for traceability upstream more to fishermen and processors. Generally, about 25 large seafood companies have traceability programs underway.

Consumer packaged goods companies have also widely leveraged standards as a means to respond to consumer demand for e-commerce offerings and product information transparency. As a result, traceability enables a consumer to research ingredients and other information that may contain allergens or conflict with dietary concerns, such as clean eating and gluten free.

Product Recalls: A Future Opportunity for Blockchain

Product recalls are additionally significantly faster with standards in place to help break down any barriers caused by proprietary numbering systems and manual communication methods. During a recall, companies that maintain a standards-based framework can pinpoint affected product down to the UPC, which batch it came from in the manufacturing process, and during which dates it may have become contaminated. Once all this information is identified, it is often shared with retailers' loyalty program members via a simple text or email.

Food traceability is improving now even without blockchain capabilities, but a strong case is being made for how blockchain represents an opportunity for traceability to move faster. Speeding up the recall process was precisely the impetus for Walmart's well-publicized blockchain traceability pilot involving mangoes. Blockchain was used in tandem with Walmart's established system of traceability based on GS1 Standards. Pallets of mangoes originating from a farm in Mexico were tagged with numeric identifiers. Every time the product made stops throughout the supply chain, their status was updated on the blockchain ledger.

After the pilot was completed, Walmart was able to pull up all relevant

traceability information in seconds, compared to what historically would take a week to procure. All the mangoes' identifying details are on the blockchain: the mangoes' weight, the exact date they were harvested, and the orchard it originated from in Oaxaca, Mexico. It even included specific details of a hot-water treatment to rid the product of any insects, the exact date the importer received the shipment, when it passed through customs, and all other transport and storage through its arrival at a Walmart store.

Enabling Transparency

Walmart is not the only company jumping on the blockchain train early. Last Thanksgiving, Cargill, the nation's largest food manufacturer, also debuted a blockchain pilot program that allowed consumers to track where their turkey originated. Described in a press release as "the first and only major turkey brand to pilot a blockchain-based solution for traceable turkey," Cargill's Honeysuckle White brand demonstrated the company's commitment to providing transparency for consumers. Consumers in select markets were able to enter an on-package code at HoneysuckleWhite.com to access the farm's location by state and county, view the family farm story, see photos from the farm, and read a message from the farmer.

This example illustrates how blockchain can work to keep secure records of a product's complete provenance. Coupled with GS1 Standards, a blockchain can record granular information about a product's transformation and journey to the consumer—ensuring systems interoperability from supplier to manufacturer to distributor to retailer.

Since not all companies are going to select the same technology partner to

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Integrating Product Traceability at the Warehouse

Warehouse execution systems provide insights into inbound and outbound inventory, allowing quick responses to upstream and downstream issues

BY **DAVE WILLIAMS**

In order to mitigate recalls and ensure product quality, food manufacturers and distributors are turning to automation. A warehouse execution system (WES) utilizing an automated storage and retrieval system (AS/RS) is one of the chief technologies making waves in efforts to reduce, if not prevent, recalls, through sophisticated track-and-trace capabilities. Further, integrating a WES into a manufacturer's supply chain management operations—connecting it to systems both upstream and downstream—is the key to tracking and tracing products end to end, from production to point of sale. This allows manufacturers to respond to problems within the production process more quickly, ensure that they are meeting regulation standards, and make adjustments to manufacturing schedules in order to meet consumer demand.

Straight from the Source

For most consumer packaged goods, ingredients may be sourced from multiple suppliers, who in turn work with multiple sources. Whether it is corn directly from a farm or flour from a bulk supplier, it is important to be able to trace these ingredients back to its source to ensure product quality and safety. Tracing ingredients back to their source also gives manufacturers in-depth insight into their supply chain—where the best ingredients are coming from and which suppliers always deliver on time.

The first step to traceability is labeling. While most farms are not required to label each piece of produce they sell per the Federal Food, Drug and Cosmetic Act, manufacturers should work with farms that label each container that leaves the farm. In addition, if the farm uses barcoding technology in its labeling process, it makes traceability more effective and efficient.

Once these materials arrive at the facility and are used to manufacture the products, they can be scanned and documented. This information, along with information that is gathered during the manufacturing process, is then imported into the manufacturer's enterprise resource planning (ERP) system where data is viewable in near real time.

Meeting in the Middle

Historically, manufacturers would use a warehouse management system and/or a separate warehouse control system to manage warehouse inventories. These two separate systems make it difficult for manufacturers to integrate warehouse inventory track-

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ing with the supply chain activities they were already tracking, including product delivery and on-shelf availability at the store level. By connecting a single WES to systems both upstream and downstream, manufacturers are able to obtain a complete view of their supply chain.

With a WES and integrated AS/RS, manufacturers can obtain real-time insight into their inbound and outbound inventory, including when a shipment arrives, when it departs, and where it is going. Therefore, if a product is recalled, it is easy to look into the system and quickly identify the batch that contained the faulty goods, pinpoint departure time and destination, and pull all items from that batch off the shelves. By identifying and pulling the exact batch, manufacturers do not waste valuable time and money removing every product from stores in an attempt to remove all contaminated items. And, with reliable data, manufacturers can prove compliance with any relevant safety regulations and confidently assure consumers that they have taken fast and thorough action to withdraw all affected products.

By providing a high-degree of product traceability, an integrated WES can help manufacturers discover and act upon issues that have caused the recall sooner. Earlier detection often allows manufacturers to better understand what product needs to be recalled, thus potentially reducing the scope of the recall effort by targeting only affected inventory.

For example, if a manufacturer ran a lot of a single product on a production line at midnight and later determined that there was a problem with those products. The manufacturing system can communicate to the WES and locate all of the products that were produced from that particular line during the specified timeframe. The quicker the response time, the greater the chance that contaminated products never leave the facility and reach store shelves.

Traceability and Recalls

If not caught prior to the products leaving the facility, utilizing a WES that is tightly integrated with other supply chain systems allows manufacturers to more quickly and easily identify products to be recalled by showing what vehicle(s) the products are on, where the products are located on the vehicle, what specific stops occurred during transit, and what other product(s) might have mixed with the contaminated products.

Companies can then utilize data to provide their customers with the information needed to identify and return the recalled product quickly and efficiently, saving both the company and its customers' time and money.—*D.W.*

In Transit

Using barcode labeling, manufacturers can track products as they are leaving the warehouse as each pallet is scanned and placed onto a truck for delivery. Advances in RFID technology and telematics systems allow manufacturers to record every movement of each product. Combined with the information gathered by the WES, manufacturers are able to trace:

- What time the product went into/out of specific controlled environments;
- What time and for how many minutes the product was out of the controlled environment;
- What time the product was loaded onto the vehicle for delivery;
- How many minutes the product was on the vehicle and at what temperature it was stored;
- What time the product reached its destination;
- How long the product sat in a particular location; and
- What time the product was put back into a controlled environment at delivery location.

Tracking products during the delivery phase is important not only to ensure products are on time, but tracing these additional variables help eliminate potential product damage or food spoilage in transit—preventing recalls and lost revenue.

At the Checkout Counter

In order for complete end-to-end traceability, ERP and WES solutions must be paired with supply chain management (SCM) systems downstream, including retail store systems. These systems keep track of on-shelf availability and point-of-sales (POS) data, which not only offer real-time insight into inventory, but also into consumer demand.

With an integrated WES, a cloud-based SCM system that is keeping track of inventory on the store level can trigger replenishment events at the warehouse. Moreover, by tying manufacturing data to a retailer's POS system, a recall might just entail an automated phone call to everyone who purchased an item, requesting it be returned to the store—instead of broadcasting it on the national news.

Online and Door-to-Door

As e-commerce continues to grow and selling centers change from brick-and-mortar stores to having a product delivered to the consumer's door, tracking and tracing products through to the consumer is even more important.

While there are always some products that are sold at super high volumes, such as coffee, most of the items at these retail distribution centers will not be high volume. In addition, the retail distributer is buying from hundreds of manufacturers. An integrated WES can help manage the inventory, as well as confirm orders are picked, and upload the data into an ERP system. The ERP then might directly communicate with customers and print out the shipping label. While the delivery destination is not a brick and mortar store, these integrated systems allow manufacturers to continue to trace products all the way through to the consumer.

The Future of Traceability

In the future, we will continue to see an increase in the number of product offerings in terms of flavors and package sizing as well as greater demand for organic, gluten-free, vegan, and locally-grown products. With more products on the market, it is imperative that manufacturers take traceability matters into their own hands by investing in automation technology to help manage their inventories.

WESs and AS/RSs will continue to advance in sophisticated track-and-trace capabilities, as well as supply chain connectivity. By implementing a tightly integrated WES into the supply chain process, manufacturers will be able to implement traceability and control requirements throughout their supply chains to respond quickly to issues both upstream and downstream—saving time, money, and, in some cases, their reputation. ■

Williams is the vice president of software development for Westfalia Technologies Inc., a provider of logistics solutions for plants, warehouses, and distribution centers. Reach him at DWilliams@westfaliausa.com.

NEW PRODUCTS

Portable Surface Sanitation

The redesigned BIOSPRAY surface sanitation system's anti-freeze technology allows for a continuous spray up to 90 minutes, without a power source. System uses CO2 delivery technology to safely apply BIOSPRAY D2 EPA registered food-grade surface sanitation in a highly calibrated stream for full coverage that reaches smaller cracks and crevices. While alcohol typically cannot be sprayed due to flammability concerns, the CO2 propellant in the BIOSPRAY device renders the alcohol inflammable, making the fine mist spray safe and capable of spanning greater distances. The company says the BIOSPRAY D2 sanitizer contains 58% isopropyl alcohol content, which completely dries off the water balance within 60 seconds after application, leaving the environment 100% free from residual moisture. **Goodway Technologies, 800-333-7467, www.goodway.com.**

Grain Moisture Tester

The D999-FR grain moisture tester has more than 250 grain calibrations with a wide temperature range (from -4° F to 158° F) for testing both frozen and hot grain. Featuring wireless data communication, the meter features 4.3-in. LCD touchscreen display that provides moisture, temperature, and test weight information. Moisture range is 5% to 50% depending on grain. Results can be achieved in less than 5 seconds. Users can synchronize and send results to smartphone, tablet, or computer using a Bluetooth connection. **Gardco, Paul N. Gardner Co., Inc., 800-762-2478, www.gardco.com.**

Sanitation Monitoring

Kikkoman's LuciPac A3 Sanitation System, distributed by Weber Scientific, measures ATP, ADP, and AMP. The A3 system technology detects food residues left behind to ensure better surface sanitation and support a more effective sanitation program that reduces the presence of resident organisms and the risks from food pathogens. It can assist in developing and improving process and risk assessment programs. For data analysis, the system comes with software that has programmable features: 100 test plans, 200 user IDs, 251 locations per test plan, and 5,000 test locations. **Weber Scientific, 800-328-8378, www.weberscientific.com.**

In Other News

Produce Marketing Association and **Purdue University's Open Ag Technologies and Systems Group** create Trellis, a produce-specific framework for electronically exchanging authenticated audit and other customer-required information among trading partners.

United Fresh Produce Association partners with **OFW Law** to provide members access to legal review of product labels, ensuring compliancy with Fair Label & Packaging Act, the Food & Drug Cosmetic Act, and applicable state labeling laws.

CERTUS expands its rapid food pathogen detection menu with initiation of an environmental *Salmonella* assay.

CAT Squared and **UniSoma** partner for launch of TacticalOps, a new planning and optimization tool to allow food manufacturers to capture and manage real-time data from the plant floor.

LexaGene Holdings completes prototype assembly for fully automated, open-access, and onsite pathogen detection platform.

3M Food Safety's Molecular Detection Assay 2—*Cronobacter* has been designated by AOAC INTERNATIONAL as a Performance Tested Method (Certificate #101703).

Hillbrush has added gray and brown to its range of color-coded cleaning tools made using food contact approved materials.

(New products continued on p. 46)

Mastering Traceability Basics ...

(Continued from p. 42)

implement blockchain, standards are the invaluable common language that can streamline the transmission of detailed product data on a blockchain. A standard called EPCIS (Electronic Product Code Information Services) is already being leveraged in the healthcare industry to record complete product chain of custody. In such a heavily regulated business environment, the track and trace of pharmaceutical products throughout the supply chain has become a requirement by law—specifically the Drug Supply Chain Security Act or DSCSA. Under this law signed by President Barack Obama in 2013, pharma companies must identify individual transactions so that all parties involved know what happened to the product, where it happened, and when. The safety of our drugs and medicines depends on the recording of this detailed information.

The food industry can learn from the implementation of EPCIS in healthcare. With the use of the same type of globally unique product identifiers, EPCIS can enable true product information transparency by providing everything about that product's chain of custody on a blockchain. As conscientious consumers scrutinize products based on their origin, sustainability, socioeconomic impact, how they were made, and other concerns, EPCIS and blockchain tell the story of the products' journey with a high degree of certainty and validity. Also, in more aspirational use cases, EPCIS and blockchain can support the Internet of Things by more efficiently transmitting data used in personalized marketing, in-home replenishment, or upselling or cross-selling beyond the sale of the products.

Deciding to Collaborate Now

Even though we may not see blockchain being used in a mainstream capacity for years to come, discussion of its benefits has created a frenzy of renewed excitement around the topic of traceability. It's important to look at the supply chain ecosystem holistically before jumping to adopt any new technology. Now is the time to lay a solid foundation for blockchain. ■

Nuce is the senior vice president, corporate development, at GS1 US, with more than 20 years of experience in retail technology. Reach her at mnuce@gs1us.org.

(Continued from p. 45)

Food Safe Motors

The stainless steel Baldor-Reliance Food Safe motors are designed around sanitary equipment principles and compatible with CIP procedures. Featuring smooth contours and advanced sealing, motors exceed IP69K for water to maximize motor life in high pressure, sanitary cleaning environments. The product line spans single and three phase ratings in foot mounted and footless configurations. According to the company, foot mounted designs meet NEMA standard mounting dimensions with continuously welded independent feet allowing easier access and clearance for proper cleaning procedures. Three phase ratings are available from stock in frame sizes 56-280T, ranging from 1/2-30 HP. Single phase ratings are available from stock in a 56C frame, ranging from 1/2-1 HP. **Baldor Electric Co., 479-646-4711, www.baldor.com.**

Thermal Desorption Systems

The TD-30 series of thermal desorption systems are available for use with the company's Nexis GC-2030 as well as its entire GCMS product line. The TD-30 series consists of two models, TD-30 and TD-30R. The TD-30 is equipped with a 60-sample carousel. The TD-30R has the ability to hold 120 samples, making it well-suited to large-volume automated analysis. Both are equipped with a retrapping function that allows split samples desorbed from the tube and loaded into the GCMS to be trapped again for potential re-measurement. An overlap function dramatically improves processing functionality by starting pretreatment of a sample while the previous sample is still being analyzed. The ability to add an internal standard in the TD-30R can allow for reliable quantitative analysis, even of trace components. **Shimadzu Scientific Instruments, 800-477-1227, www.ssi.shimadzu.com.**

Digital Sorter

The VERYX B210, featuring an inspection area over 80-in. wide, can maximize throughput on high-capacity lines. Recognizing objects' color, size, shape, and/or structural properties, the sorter removes foreign material and product defects to improve product quality while virtually eliminating false rejects to increase yields. It offers a production capacity in excess of 50,000 lbs. of product per hour, depending on the application. Sorter optimally singulates product on the belt to improve sorting accuracy. The B210 is ideal for wet and frozen potato strips and specialty potato products as well as fresh and frozen fruits and vegetables, leafy greens, potato chips, and other snack foods, confections, seafood, and more. **Key Technology, Inc., 509-529-2161, www.key.net.**

Wiley Food Technology

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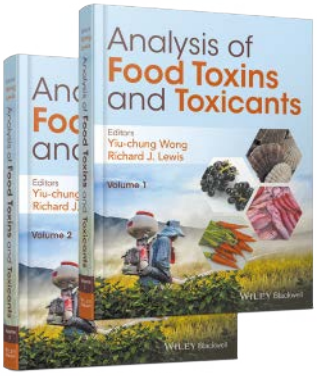

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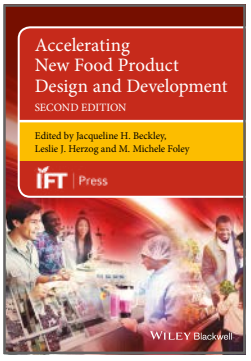

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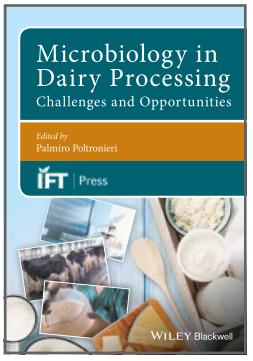

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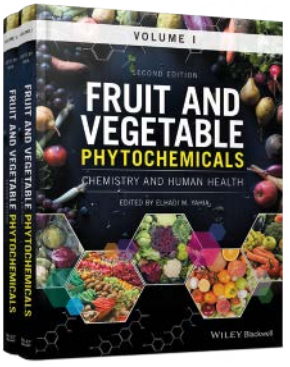

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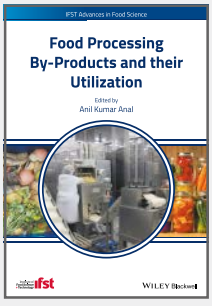

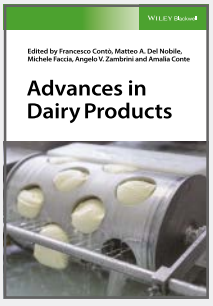

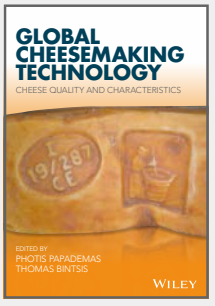

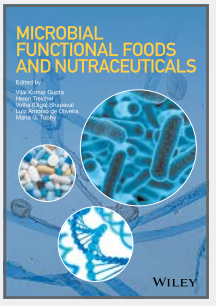

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