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Volume 20 Number 5
OCTOBER/NOVEMBER 2013

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Features

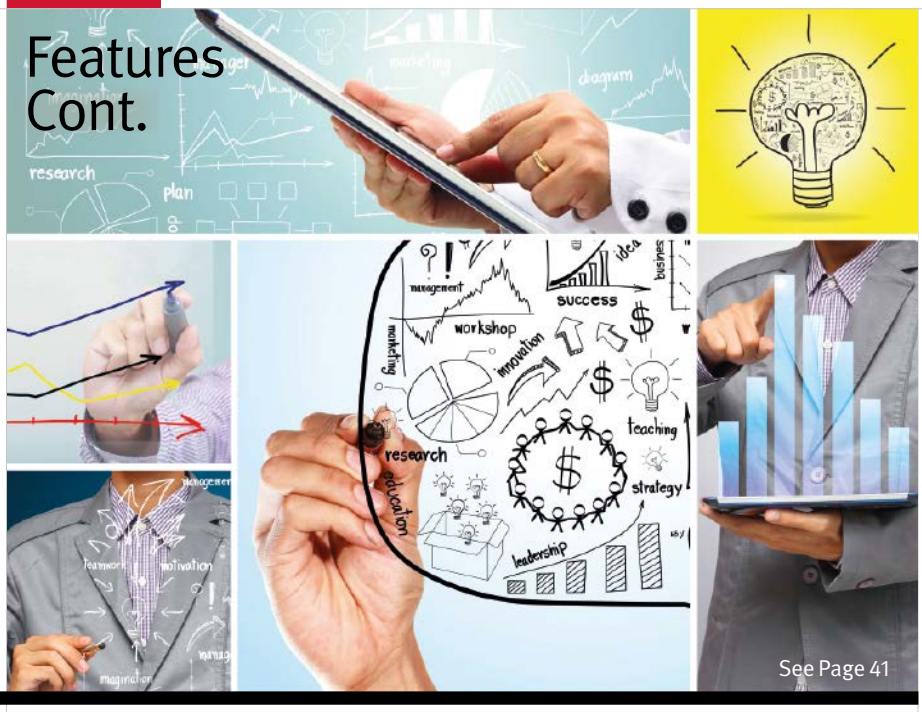
Safety & Sanitation

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. Subscription for U.S. is $126 per year. International subscription is $160.

Food Quality & Safety is a proud member of: United Fresh Produce Association
Folio Ozzie and ASBPE award winner for editorial and graphics excellence.

POSTMASTER: Returns and address changes to *Food Quality & Safety* magazine, PO Box 9051 Maple Shade, NJ 08052-9651

Features Cont.



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From The Editor

All your hard work in ensuring the quality and safety of consumers' food supply could, quite literally, be getting tossed in the garbage. A new report on food expiration date confusion co-authored by the Natural Resources Defense Council and Harvard Law School's Food Law and Policy Clinic found that more than 90 percent of Americans may be prematurely tossing food because they misinterpret food labels as indicators of food safety. This confusion stems from poorly regulated and inconsistent labels with terms like "sell by," "best used by," and "expires."

There are indeed two main categories of food labeling: Labels intended to communicate to businesses and those for consumers. But they aren't always easy to tell apart and neither indicates food's safety. "Sell by" dates are geared towards retail stock control and don't imply the food is bad on that date. "Best before" and "use by" dates are for consumers, yet are sometimes simply a manufacturer's estimate of a date after which food will no longer be at peak quality; not always an accurate date of spoiling.

Adding to confusion is the fact that date labeling laws differ from state to state with some not even requiring food manufacturers to carry use-by dates.

Inconsistent labels undermine the intent of date labeling. As mentioned, 91 percent of consumers occasionally throw food away based on the "sell by" date out of a mistaken concern for food safety. (I must admit to being one of those paranoid people constantly checking labels and having no qualms about throwing out food if the date is passed due, regardless of the type of label.)

Date labels are not only creating problems among consumers—supply chain efficiency is suffering as workers are also misinterpreting these labels.

Thus the report calls for the government to establish a new standardized system for food date labeling. The authors also recommend some changes that food producers and retailers can implement to work toward this goal, including creating a labeling system that communicates clearly with consumers by using consistent language; differentiating between safety- and quality-based dates; and employing more transparent methods for selecting dates. They also suggest making the "sell by" dates invisible to consumers and increasing the use of safe handling instructions and "smart labels" that use technology to provide additional information on the product's safety.

Food processors are encouraged to take these recommendations seriously as establishing a reliable and consistent date labeling system can ensure all their hard work doesn't get tossed aside.

Marian Zboraj
Editor

Food Quality & Safety
FARM TO FORK SAFETY

PUBLISHING DIRECTOR Lisa Dionne, ldionne@wiley.com
ASSOCIATE PUBLISHER Ken Potuznik, kpotuznik@wiley.com
EDITOR Marian Zboraj, mzboraj@wiley.com
DESIGN Maria Ender, mender@wiley.com
PRODUCTION Claudia Vogel, cvogel@wiley.com
Christiane Potthast, cpotthast@wiley.com
Elli Palzer, palzer@wiley.com

Advertising Sales Manager
SCIENCES, CORPORATE SALES, AMERICAS
Joe Tomaszewski
111 River St. 8-01
Hoboken, NJ 07030-5774
(201) 748-8895 • Cell: (908) 514-0776
jtomaszews@wiley.com

Sales Office
U.S./CANADA/INTERNATIONAL
Ken Potuznik
29822 N 51st Place, Cave Creek, AZ 85331
(480) 419-1851 • fax (480) 718-7719
kpotuzni@wiley.com

Editorial Office
111 River Street, Hoboken, NJ 07030-5774, USA

Reprints: E-mail kpotuzni@wiley.com
Editorial Submissions: E-mail mzboraj@wiley.com

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

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LETTERS TO THE EDITOR

The Produce Industry's 'Barcode' of Approval

AUGUST/SEPTEMBER ISSUE

Really liked the article on PTI by Dan Vache (met him at the United Fresh and he is a passionate leader in the Produce Industry)... Traceability and Food Safety are paramount issues in the Meat and Produce Industry. This is a concern to producers, processors, retailers, and CONSUMERS. Not saying the other verticals in the Food Industry don't have the same concerns, but we are talking about products that are often handled raw throughout the supply chain and have short shelf lives here. Great to have organizations like United Fresh and excellent publications that support the Food Industry opposed to large media outfits that undermine it.

—Allan Hills, hiring consultant, CPG Executive Search Inc.

Women's Role in Reforming Food Safety

AUGUST/SEPTEMBER ISSUE

Thought the article was very good and certainly opened my eyes up a bit as to what women had to put up with back in the day. (The University did not award BAs to women, so she received a "certificate of proficiency." What?!)

—Sandra Sheridan, REHS, senior environmental specialist, Kalamazoo County Health Department

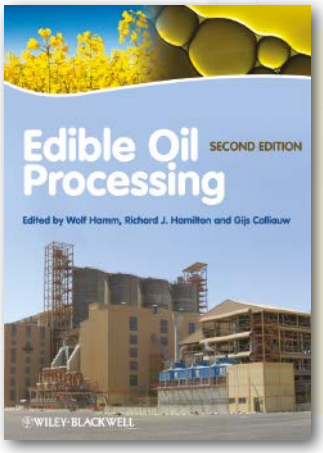
Getting a Handle on Foreign Materials

AUGUST/SEPTEMBER ISSUE

I have spent 25 plus years identifying foreign materials allegedly found in foods. Over 30,000 exhibits—always finding new complaints. A good number of the complaints would end up in court, but many more were settled due to the high costs involved in defending them. There are many ways to identify the most likely source and, maybe more importantly, whether they were packed with the food or introduced after opening the packaging. A huge challenge to the industry as a whole.

—Robert Callaway, owner and chief scientist, Callaway Food Forensics

Edible Oils
Science & Technology Resources

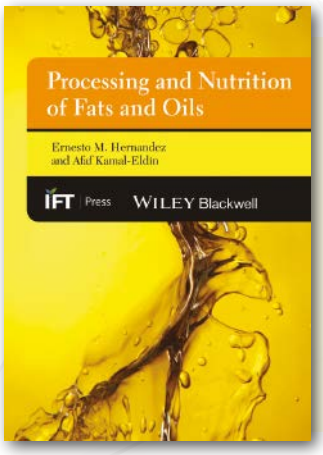


Edible Oil Processing, 2nd Edition

Wolf Hamm, Richard J. Hamilton, Gijs Calliauw

978-1-4443-3684-9 • Hardcover • 342 pages • August 2013

This second edition of *Edible Oil Processing* presents a valuable overview the latest technologies in edible oils and fats processing, addressing new environmental and nutritional requirements as well as the current state of world edible oil markets.

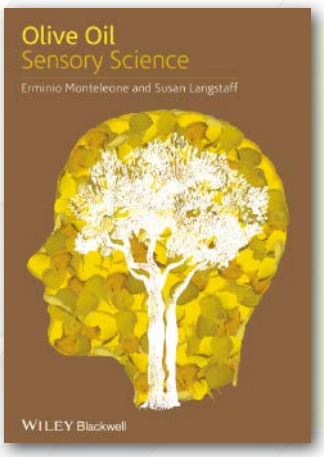


Processing and Nutrition of Fats and Oils

Ernesto M. Hernandez, Afaf Kamal-Eldin

978-0-8138-2767-4 • Hardcover • 276 pages • October 2013

Processing and Nutrition of Fats and Oils reviews current and new aspects of fats and oils processing, how the nutritional properties are affected, and how fats interact with other components and nutrients in food products.



Olive Oil Sensory Science

Erminio Monteleone, Susan Langstaff

978-1-118-33252-8 • Hardcover • 402 pages • December 2013

Olive Oil Sensory Science details the appropriate sensory methods for olive oil optimization, product development and consumer testing.

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NEWS & NOTES

Food Safety Education Materials for Kids

Developed by Partnership for Food Safety Education, the "Fight BAC! at Picnic Park" program helps kids, parents, and teachers get involved in learning about preventing food poisoning. It includes the Perfect Picnic game for iPhones and iPads and informational materials to help teach important food safety basics. The Partnership for Food Safety Education is supported by the Food Marketing Institute, Grocery Manufacturers Association, NSF International, the Produce Marketing Association, and ServSafe, among other industry associations, professional societies in food science, nutrition and health, and consumer groups.

Outbreak Guidelines for Food Establishments

The Council to Improve Foodborne Outbreak Response's (CIFOR) new *CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments* helps outline, clarify, and explain the recommended role for retail food establishments during a foodborne illness outbreak investigation and what they can expect after being notified of an outbreak. It offers a step-by-step approach that companies can take during the different phases of an investigation, including preparing an establishment to respond should an outbreak occur, identifying signs of a potential outbreak, helping government officials to investigate, and following up after an investigation.

Changes to Pre-Harvest Harmonized Standards Now Official

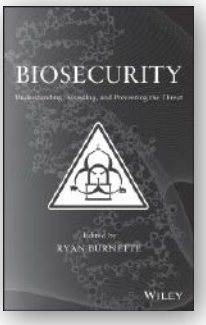
The Produce GAPs Harmonization Initiative Technical Working Group approves changes to the Field Operations and Harvesting Harmonized Food Safety Standards. The new version of the Harmonized Standards will become obligatory on November 1, 2013. In order to have one audit by any credible third party and acceptable to all buyers, the Initiative developed food safety Good Agricultural Practices standards and audit checklists for pre- and post-harvest operations, applicable to all fresh produce commodities, all sizes of on-farm operations, and all U.S. regions.

FDA Defines 'Gluten-Free' for Food Labeling

The FDA publishes a new regulation defining the term "gluten-free" for voluntary food labeling to provide a uniform standard definition to help those Americans who have celiac disease. The definition requires that, in order to use the term "gluten-free" on its label, the food must contain less than 20 ppm of gluten. The rule also requires foods with the claims "no gluten," "free of gluten," and "without gluten" to meet the definition for "gluten-free." Food manufacturers will have a year to bring their labels into compliance with the new requirements.

Environmental Impact Statement on Produce Rule

The FDA intends to prepare an Environmental Impact Statement (EIS) that will evaluate the potential environmental effects of the proposed rule Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption. FDA is also announcing the beginning of a "scoping process" to determine relevant issues that will influence the scope of the environmental analysis. The Agency doesn't anticipate that the EIS will delay final rule deliberations but will help by generating additional data and analysis and providing opportunity for stakeholder engagement. Comments are due by November 15, 2013.



Biosecurity: Understanding, Assessing, and Preventing the Threat

Published by Wiley, the new *Biosecurity* book is edited by Ryan Burnette, PhD, director of Alliance Biosciences. The book explores how to assess and prevent biosecurity threats to protect public health and national security. It discusses the nature of biosecurity threats to research laboratories as well as to agriculture and food. By exposing major flaws in global biosecurity thinking, the book sets forth a clear pathway to correct those errors and build stronger biosecurity programs.

Business Briefs

Eldon James Corp., manufacturer of plastic tubing and connectors, launches its food and beverage division—EJ Beverage.

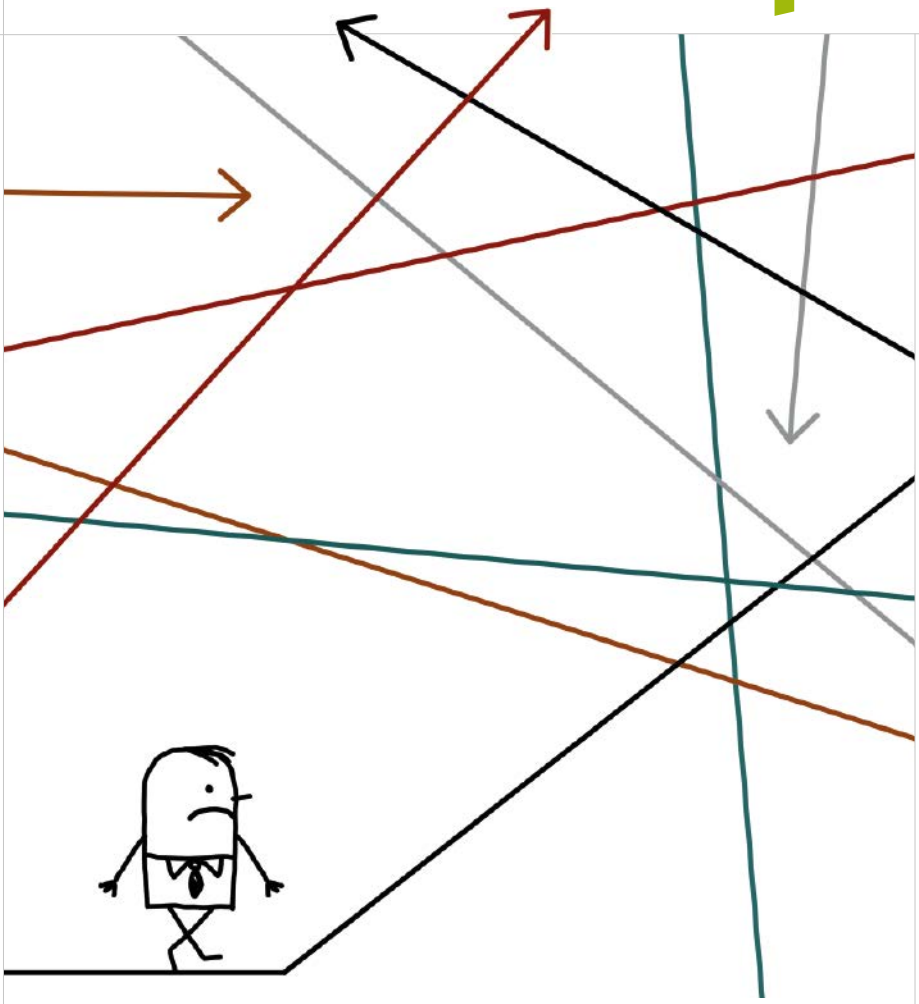
Kirkegaard & Perry Laboratories, Inc. forms new development relationship with **Vivione Biosciences Inc.** to allow Vivione to accelerate commercialization of the detection kits used in its RAPID-B platform.

D.D. Williamson receives certification by GFSI for its natural coloring manufacturing site in Port Washington, Wis.

Plascon Group's flexible packaging manufacturing plant in Traverse City, Mich., achieves BRC Global Food Safety Certification.

GFSI launches new Retail/Wholesale Technical Working Group to draft key requirements for inclusion in the GFSI Guidance Document.

FSMA Update



Getting Imported Foods on the Straight and Narrow

With globalization adding more complexities to supply chain, FDA's recently proposed rules aim to assure imported products meet the same standards as those produced domestically

BY **TED AGRES**

Major U.S. food industry associations and consumer groups are guardedly optimistic that the FDA's recently proposed regulations on import safety and third-party auditors will improve the safety of food products obtained from foreign countries. But experts also warn that the additional costs of complying with the new rules—including obtaining audits and certifications, recordkeeping, and reporting—will be passed onto consumers through higher prices.

The draft regulations, published in the *Federal Register* on July 29, 2013 to implement portions of the Food Safety and Modernization Act (FSMA), are intended to hold imported food to the same safety standards as domestically produced products. But there are also concerns that foreign companies will be held to more stringent requirements, such as undergoing audits by independent third parties. This, some experts say, might spark complaints from major trading partners because U.S. companies are not subject to the same requirements.

"If the U.S. is to stay commensurate with the World Trade Organization, whatever the U.S. government will require of foreign facilities also needs to be required of domestic companies," says Craig Henry, a director at Deloitte & Touche LLP. "However, the third-party accreditation rule focuses only on foreign facilities. Therefore, it may be possible for U.S. trading partners to raise concerns unless U.S. exporters are held to the same standards," Henry tells *Food Quality & Safety* magazine.

David Acheson, MD, director of the food and import safety practice at Leavitt Partners and a former FDA associate commissioner of foods, agrees. "We may see some pushback on trade issues. The biggest red flag is that we're going to require importers to do different things and, on the face of it, it isn't equal," Acheson tells *Food Quality & Safety*. "We will see more noise and traction around that than anything else."

Under the new proposed rules, U.S. importers, for the first time, must verify that their suppliers are meeting U.S. food safety requirements no matter where food is produced. In general, importers would be required to have a plan in place for each imported food, including identification of likely hazards associated with each food, and conduct activities to reasonably assure that those hazards are adequately controlled. "These proposed rules, as envisioned by the statute, rely on strong

(Continued on p. 14)

(Continued from p. 13)
partnerships with industry and foreign governments to ensure the safety of their food products," says Michael R. Taylor, deputy FDA commissioner for foods and veterinary medicine.

The need for such controls is growing. About 15 percent of all U.S. food is imported, including 80 percent of seafood, about 50 percent of fresh fruits, and 20 percent of fresh vegetables. Despite this volume, FDA physically inspects less than 2 percent of all food imports. The two new rules "will help prevent food safety problems before foods arrive in the U.S. instead of relying primarily on catching problems at the port," Taylor tells *Food Quality & Safety*. "They are central to the FDA's vision of a system that provides significantly elevated assurances about the safety of food consumed in the United States moving in international trade and creates a level playing field for producers and processers in the United States and abroad."

New Requirements

FSMA requires FDA to create the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) and Accreditation of Third-Party Auditors. The FSVP defines U.S. importers as either the U.S. owner or consignee at the time of entry, the U.S. agent, or the U.S. representative of the foreign owner or consignee. The importer is required to develop, maintain, and follow a verification program for each food it imports (unless the food is exempted). Some of the required activities include the following.

Compliance status review. Before importing the food and periodically thereafter, importers must review the compliance status of the food and the supplier. This includes the existence of any FDA warning letters, import alerts, and certain certification requirements.

Hazard analysis. Importers must identify and analyze any hazards that are reasonably likely to occur in each food and evaluate the severity of illness or injury that might develop.

Verification activities. To provide assurances that risks are controlled, importers must conduct verification activities such as onsite auditing of foreign suppliers; periodic or lot-by-lot sampling and testing; periodic review of foreign supplier food safety records; or other "appropriate" risk-based procedures. Instead of performing an audit, an importer may use an FDA inspection or inspection by a recognized food safety authority in the foreign country if it has been conducted within the previous 12 months.

Corrective actions. Importers must review any complaints they receive, investigate the cause or causes of adulteration or misbranding, take corrective actions, and revise their FSVPs if deemed inadequate.

Periodic reassessments. Importers must reassess their FSVPs at least every three years or sooner if they become aware of new information about potential hazards, such as changes to the source of raw materials or product formulation.

> This might spark complaints from major trading partners because U.S. companies are not subject to the same requirements.

Recordkeeping. Importers must keep records documenting all of the above.

The food safety law exempts from FSVP imported juice and seafood from facilities that comply with HACCP regulations because importers are already subject to supplier verification requirements. "Requiring supplier verification for these foods under the FSVP regulations would be duplicative," Taylor explains. Modified FSVP requirements apply to imported dietary supplements and components; food imported by "very small" importers or from "very small" foreign suppliers (having no more than $500,000 in annual sales); or food from a foreign supplier in good standing in a country whose food safety system is recognized by FDA as equivalent to that of the U.S. (such as New Zealand).

Third-Party Auditors

FSMA also requires FDA to establish a program for the Accreditation of Third-Party Auditors for foreign food facilities. In this, FDA will recognize accreditation bodies which, in turn, will accredit third-party auditors to conduct food safety audits and issue certifications for foreign facilities and food. The FDA is also developing draft model standards by which organizations would qualify for accreditation, such as minimum education and experience levels for their auditors and audit agents. By law, FDA is to look to already existing standards, such as international voluntary consensus standards and current practices of accreditation bodies.

The third-party auditor could be a foreign government, a foreign cooperative, or other third party as long as it has legal standing and meets other standards, such as for competency. Third-party auditors are to conduct "vigorous audits," submit reports of audits used for certification purposes to the FDA, and notify the agency if they find any serious public health risks. This program will become the basis for the upcoming Voluntary Qualified Importer Program, which will allow expedited review and entry into the U.S. of food produced by certified foreign facilities. While the FSVP does not require importers to use accredited third-party auditors, the FDA anticipates that importers may increasingly rely on them once the program is in place.

Pros and Cons

Reaction to the two rules from industry and trade groups has been generally, if cautiously, favorable. David Gombas, senior vice president for food safety and technology at United Fresh Produce Association, says, "Initially we don't see any surprises in FDA's draft rules on imported foods and third-party auditor accreditation. However, it's important that we thoughtfully review them in a line-by-line fashion, including analysis of their interaction with other FSMA draft rules, to ensure they advance food safety and are workable for the industry."

"With the release of the draft import rules, we are one step closer to the safer food supply," says Sandra Eskin, director of food safety at Pew Charitable Trusts. "By holding overseas producers to U.S. food safety standards, the new rules would establish a level playing field that would also benefit U.S. businesses, farmers, and food processors," she said in a statement.

"Supplier verification means that companies should know who they are buying from—not just their name and address, but their food safety practices," says Caroline

Smith DeWaal, food safety director at the Center for Science in the Public Interest. "When these rules are eventually implemented they will, at long last, give the FDA strong tools to improve the safety of imported foods."

"Globalization has added additional layers, fragments, and complexities to the food supply chain, which have increased the number of points where the supply chain is vulnerable to food contamination, counterfeits, and mislabeling," says Michael Lucas, CEO of track and trace provider Frequentz. The new rules "show a major shift in thinking in the way the government works to keep food safe—stressing prevention and making businesses more responsible for the food they are selling or importing by proving that they are using good food safety practices," he tells *Food Quality & Safety*.

But others see a downside because of added complexity and costs. "There is a presumption in this foreign supplier verification proposal about the extent of influence and control an American importer will have over his suppliers," says Susan Kohn Ross, an international trade specialist at the law firm of Mitchell Silberberg & Knupp in Los Angeles. "While the large companies will be able to comply with some adjustments to existing procedures, this proposal is a real headache, recordkeeping nightmare, and cost burden for small and medium-sized companies," she wrote in a recent analysis.

The FDA estimates compliance with the new rules will cost the U.S. food industry about $500 million annually.

The FDA estimates compliance with the new rules will cost the U.S. food industry about $500 million annually. "For sure, increased costs will be passed onto the consumer for these compliance mechanisms to take place," Acheson says. And while some food importing companies have been anticipating the rules, others have not. "For many importers, the rules will come as a bit of a surprise. We're going to see confusion, surprise, and concern," Acheson predicts.

The two rules are open for public comment until November 26, 2013. The FDA has extended the deadline for commenting on two earlier draft regulations—for produce safety and preventive controls for human food—until November 15, 2013. This was done to give people time to consider how the four rules interrelate. (A fifth FSMA rule on preventive controls for animal food is expected to be issued by November 2013.) ■

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

Industry Insights

Will FSVP Shed Light on Food Safety or Keep it in the Dark?

Deciding which of the two competing options under proposed FSVP rules will be more beneficial for food processors, foreign stakeholders, and consumers

BY **SHAWN STEVENS**

It's the things we can't see that we fear most. In the food industry, our fear of invisible pathogens is really no different than the fear of the basement we had as a child (or in my case, as an adult). We were terrified of going down the basement stairs because we couldn't easily see and thus not easily verify whether there were any ugly creatures waiting in the shadows for the opportunity to pounce. Human instinct has made us fearful of such places because it is difficult to protect against threats we simply cannot see. Fortunately, the solution, in most cases, was to quickly "turn on the lights."

Fears of the unknown have driven substantial change in the food industry. In the U.S., industry responded in a similar fashion to the threat of invisible microorganisms by "turning on more lights." More food companies are testing more ingredients, equipment, and finished products—and now more harmful pathogens are being found.

Similar concerns exist with respect to the overall safety of foreign food product imports. If we stand on the beaches of California, we cannot see what's happening on the opposite shore. The inability to see clearly (or at all) what is occurring with respect to the growing, processing, and export of incoming foreign foods causes both industry and government to become increasingly fearful of the unknown.

There are political reasons as well. More than 15 percent of the food consumed in the U.S. each year is imported from foreign shores. And this number is growing larger. Increasingly, more consumers are beginning to question where their food is coming from and what is being done by government and industry to ensure its safety. This is especially true when foreign food products have been involved in an increasing number of food safety scandals. Headlines have included stories about melamine in pet food, mercury in baby formula, and the misbranding of meat.

So what is the solution? Here too, rather than urging companies to stop buying foods from foreign countries, FDA has proposed instead to "turn on a few more lights." Moving forward, FDA will require all food companies in the U.S. who import foreign food products to take steps designed to ensure the food they are importing is as safe as it can be.

Well, maybe. No one expected that when the FDA published its proposed Foreign Supplier Verification Program rules, FDA would actually publish two sets of rules and invite key stake holders to, in effect, "vote" on which of the two they liked best.

On the one hand, the FDA's approach might be viewed as commendable for letting consumers, industry, and politics guide the debate; but on the other hand, the agency appears to be sidestepping its responsibility of issuing regulations which, in its expert judgment, are best suited to keep industry strong and consumers safe. With that said, whether motivated by a fear of being perceived by suppliers, industry, and consumers as doing "too little" or being perceived as doing "too much," FDA seems to be hedging its bets by proposing two alternatives.

Two Options

For simplicity sake, let's call the two sets of proposed rules "Option 1" and "Option 2." In its most simple form, Option 1 creates stringent auditing requirements on higher-risk foods and less stringent requirements on low-risk foods. Option 2

simply creates less stringent requirements on all foods, regardless of risk.

Under Option 1, if a food product is subject to a hazard that is reasonably likely to occur and there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death, then the importer must ensure the foreign supplier is being audited at least once annually by a qualified individual. A qualified individual is a person with the necessary education, training, and experience to conduct a food safety audit which will ensure the foreign supplier is complying with the regulations.

If, however, a food product under Option 1 is subject to a hazard for which there is not a reasonable probability that exposure will cause adverse health consequences or death, the requirements are far less stringent. In these circumstances, the importer will have the ability to choose for itself which verification procedure from a list proposed by FDA it will use. These less stringent verification procedures include *periodic* onsite auditing; *periodic* lot-by-lot sampling and testing of the food; *periodic* review of the foreign supplier's food safety records; and any other procedures which, in the discretion of the importer, are deemed "appropriate."

Under Option 2, regardless of the level of risk associated with a food product, an importer will be able to establish compliance by merely selecting one of the less stringent verification procedures outlined above. Thus, the real difference between Option 1 and Option 2 is that, with respect to food products that carry a reasonable likelihood of causing adverse health consequences or death, under Option 2 there is no auditing requirement. Instead, importers simply could choose to periodically review the supplier's food safety records, to periodically test the supplier's products, or to follow any other verification procedures the importer deems "appropriate."

Life or Death Decisions?

In light of the differences between options, how could choosing one or the other really be a matter of life or death? The answer really depends upon whether the question is viewed through the lenses of foreign product suppliers, importers, or consumers.

From the perspective of foreign food product suppliers, Option 2 may be interpreted as the only real option. Under Option 2, importers could demonstrate compliance, regardless of the capabilities or qualifications of the foreign supplier, by "periodically" testing incoming products or selecting one of the other less stringent procedures (or, I guess, by simply making up one of its own). If Option 1 were selected, however, a large number of existing foreign food product suppliers would likely be forced out of business.

This is because many foreign suppliers, in order to export to the U.S., would be forced to pass a physical audit demanding them to demonstrate actual compliance with each of the requirements of the Food Safety Modernization Act (FSMA), including the requirement that they develop and implement a science-based written preventative control program. Foreign suppliers would also be required, in order to pass that audit, to comply in other respects as well, demonstrating they have adequate prerequisite programs, equipment, and facilities. Because many foreign suppliers would be unable to satisfy the proposed auditing requirements, they would also be unable to export foods to the U.S. Thus, from the perspective of many foreign food product suppliers, the choices being proposed by FDA raise literal questions of life and death.

> Many foreign food product suppliers who remain unable to pass a simple audit will continue to exist unregulated and unsupervised in the shadows.

From the standpoint of the importer, the answer is less clear. On the one hand, the audit requirements should be welcome from the standpoint of sophisticated companies. Requiring audits of all foreign suppliers of high risk foods will enhance incentives for foreign suppliers to upgrade their food safety systems, will ensure the increased safety of all high-risk foods, will promote the application of uniform standards applicable to all foreign suppliers, and will level the competitive playing field for all importers. On the other hand, the cost of foreign food product imports will likely increase (at least in the short-term) as companies work to achieve compliance, and importers will likely be burdened with increased regulatory costs as they themselves work to ensure their foreign suppliers are FSMA compliant and being properly audited by qualified individuals. Bottom line is everyone wins, but foreign imports become a bit more costly.

From the standpoint of consumers, Option 1 is without question the *only* option. As noted above, we often fear what we cannot see. Option 1, for all practical purposes, is the only option that actually "turns on the lights" with respect to foreign food products. If enacted, each foreign supplier of high risk foods will be required to have an audit. In order to pass that audit, the foreign food product supplier will be required to establish it satisfies, with only a few exceptions, each of the more stringent requirements of FSMA. Unless this option is selected for enforcement by FDA, importers will be able to select any one of the less stringent verification procedures requiring only "periodic" checks of records or testing, and many foreign food product suppliers who remain unable to pass a simple audit will continue to exist unregulated and unsupervised in the shadows. From the standpoint of the consumer, choosing the wrong path could have catastrophic consequences.

So, if you join me in the basement to escape for a moment the politics of global food safety and foreign trade (which in this business is nearly impossible to do), I offer the following advice: If the real goal is to improve the safety of foreign food product imports, then Option 1 is the best choice. Option 1 will quickly and brightly illuminate noncompliant suppliers, will improve the quality and safety of all imported foods, and, in doing so, will save lives.

FDA has given stakeholders until November 26, 2013 to comment on the two competing rules. I urge you to comment on the option you like best, but warn that the choice you make could, quite literally, mean the difference between someone's life and death. ■

Stevens, an attorney at Gass Weber Mullins LLC in Milwaukee, Wis., counsels food industry clients nationally on food safety regulatory and liability issues. He can be reached at stevens@gasswebermullins.com.

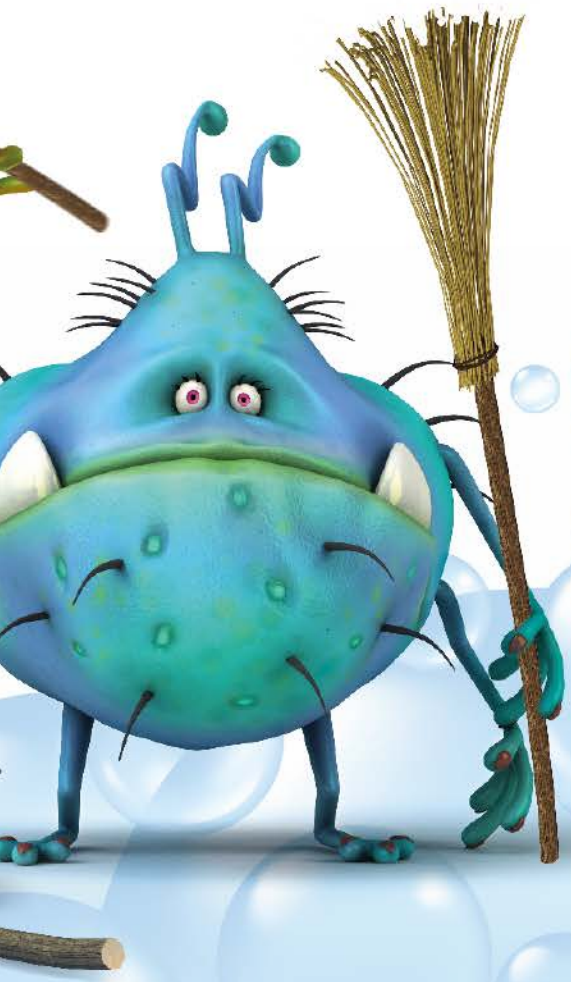
KEEP IT CLEAN

Sanitation will play a big part in FSMA implementation, requiring proper disinfecting practices to reduce microbial contamination on equipment and other surfaces BY **KEVIN KEENER**

The Virtual Food Systems Training Consortium (VFSTC) is a coalition of four universities that is creating online training for food inspectors from federal, state, local, territorial, and tribal agencies. Inspectors of FDA-regulated foods will be able to get up-to-date training without taking time away from work and costing already-strapped states a lot of money. As the "subject matter expert" for two online courses about sanitation, I am detailing the best practices that inspectors of FDA-regulated foods will be looking for when they inspect a food procesing facility.

The Food Safety Modernization Act (FSMA) gives the FDA increased regulatory authority, and there is a good possibility that new regulations might require written hazard-control plans for food production facilities that have not required such plans in the past. FSMA includes an exemption based on income and sales, but recent discussions with state regulators suggest many states will implement regulations requiring small, exempt processors to meet the federal requirements.

Some of the regulations that will define the law are still a big question mark, but it might be a good idea to look at your current procedures, and companies that do not have a hazard analysis plan in place should get ready to implement a written plan. FSMA's main emphases are prevention, inspection and compliance,



response, and imports. Under "prevention," you will have to evaluate hazards and then identify preventative steps and controls to reduce those hazards, which means you need to know the basics of disinfection.

The Cleanup

Cleaning is the physical removal of visible soil from surfaces, kind of a "touch-up." But remember—just because a surface appears clean, it might still be teeming with microorganisms. Sanitizing, then, is the treatment of a surface to significantly reduce the number of microorganisms. What we call "sanitation" is a combination of the two.

Figure 1 (p. 20) illustrates the objectives in each step of the sanitation process. We are looking at the remaining soil and bacteria attached to a food contact surface, with the understanding that the initial "dry" clean and rinsing steps have already been completed. On the far left, notice the bacteria in the white area being protected beneath the overlying layer of soil. Once a cleaning agent is applied, along with some mechanical action and/or time and temperature requirements, followed by another rinse, we now see the removal of the soil along with a significant portion of the microbe population.

This first step, cleaning, is extremely important and removes approximately 90 percent of all microbes on a surface. After cleaning the processing equipment, floors, and walls, all visible traces of soils and contamination have been removed—but invisible microorganisms tightly adhering to equipment areas and surrounding surfaces still pose a contamination risk. These surfaces must be disinfected to kill all microbial populations.

The Role of Disinfectants

Sanitizers are the last line of defense against pathogens in a food manufacturing facility; when a sanitizer is applied to the surface after cleaning, the microbe population is reduced even more to a very low, safe, acceptable level, providing a surface nearly free of microbial contamination. Basically, disinfection is the process of destroying pathogens, their toxins, and associated vectors via heat, chemical treatments, or ionizing radiation. The disinfectant is the agent that delivers the disinfection.

The FDA defines sanitization as "the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999 percent reduction of representative disease microorganisms of public health significance." FDA regulates chemical sanitizers as an indirect food additive and includes conditions of use specifications.

There are three commonly used methods of sanitation: Thermal, radiation, and chemical. The Environmental Protection Agency (EPA) regulates sanitizers for all applications, from health care to food manufacturing. To be an EPA-registered sanitizer (whether thermal, radiation, or chemical) for a food contact surface, test results for a product must show a bacterial reduction of at least 99.999 percent over the parallel control count within 30 seconds for the bacteria *E. coli* and *S. aureus*.

Obviously this is a big subject, so I am going to focus on chemical disinfection, a very common and effective way to sanitize equipment or other surfaces. Chemical sanitizers to be used on previously cleaned food contact surfaces require a 5-log reduction of *S. aureus* and *E. coli* and are registered by EPA for efficacy.

Sanitizing Solutions

A sanitizing solution consists of a chemical compound that is mixed with water and applied to a surface. This chemical attacks and kills microorganisms present on the contact surfaces. The most common chemical compounds utilized as effective sanitizers are chlorine, iodine, quaternary ammonium (known as "QUATS"), and peroxide.

Chemical sanitizers available for use in food processing vary in their chemical composition and their activity, and understanding the individual characteristics of each chemical is the key in choos-

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ing the best sanitizer for a particular job. The ideal sanitizer has broad-spectrum microbial destruction properties, with a uniform rapid kill against vegetative bacteria, yeasts, and molds. It must also be effective in the presence of organic matter, detergent residues, water hardness, and pH variability.

The ideal sanitizer is also nontoxic and nonirritating, soluble in water, noncorrosive, has a low level of acceptable odor or is odorless, and is stable in both its concentrated form or at its diluted usage level. Application methods vary from product to product, and recommended directions for use are listed on each sanitizing product. Sanitizers should be easy-to-use, readily available, and inexpensive.

Chlorine Sanitizers. These sanitizers are commonly utilized in the food industry because they are inexpensive, fast acting, and effective against a variety of microorganisms. There are several different chlorine compounds that are used, including hypochlorite, organic and inorganic chloramines, and chlorine dioxide. Chloramines are formed from the addition of ammonia to hypochlorous acid, forming chloramine and water.

The term "available" or "free" chlorine is used in evaluating a chlorine sanitizer's level of effectiveness. "Free chlorine" is the amount of chlorine available to act as a sanitizer. One thing to remember, however, is that chlorine will bind to organic soils or evaporate and, as a result, becomes unavailable in the sanitation

VFSTC AND KEVIN KEENER

Figure 1.

process. For example, residual soap will negate a chlorine solution's sanitizing effectiveness, underscoring the importance of the cleaning process that precedes the disinfection process.

Municipalities that treat drinking water with chlorine target a minimum residual of 1 part per million, or ppm, of free chlorine. Most public spas and hot tubs must contain 1.5 to 3 ppm of free chlorine. In the food industry, a chlorine solution of 50 ppm or less is not considered a sanitizer, so 50 ppm of chlorine is the minimum requirement imposed on a sanitizer for a food facility. But remember—too high a concentration of free chlorine results in chlorine residues. Therefore, generally, the maximum usage level for equipment (without rinsing) is 200 ppm.

Chlorine efficacy is both temperature and pH-sensitive. At high water temperatures, chlorine quickly evaporates, rendering the solution ineffective. The pH also affects a chlorine solution's efficacy, with chlorine solutions being most effective at pH levels around 6.5. At a lower pH, the chlorine solution can be corrosive to materials and surfaces. Chlorine's effectiveness drops very quickly as pH rises above neutral pH of 7. Because chlorine is corrosive and a skin irritant, its use poses potential health hazards.

Iodine Sanitizers. The most effective iodine-containing compounds used in the food processing industry are iodophors. Iodine sanitizers are effective against most microorganisms, including bacteria, yeasts, and molds at a usage level of 12.5 to 25 ppm. Unlike chlorine, iodophors are effective under a wide pH range (pH 2 to 10); however, they are primarily utilized under low-pH conditions (in the acidic range). Remaining soil on surfaces will quickly bind chlorine, making it ineffective. Therefore, iodine sanitizers are more stable where there is residual soil in the environment.

The advantages to iodine sanitizers are that they can be used at much lower pH levels and that they are less corrosive than chlorine. The efficacy of iodine sanitizers is temperature dependent, however. At high temperatures (above 80 degrees Celsius), iodine becomes very corrosive. At temperatures below 50 degrees Celsius, it is unstable and ineffective.

The disadvantage to iodine sanitizers—and it is a big one—is that iodine sanitizers are two to four times more costly than chlorine sanitizers, depending on the formulation. Another drawback is that the significant contact or residence time required for an effective microbial kill is longer (up to 30 minutes). In addition, iodine sanitizers have an odor that some people find unaccept-

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able, and iodine solutions can stain, leaving equipment surfaces yellow or orange.

QUATS. The QUATS family of tertiary amines is identified in part by its different chemical side groups. A variety of QUATS are available for use in the food processing industry, but bromine or chloride types are the most commonly utilized. QUATS readily adhere to the surface of microorganisms and are considered to be the most efficient and effective sanitizers used in the food industry. They are very effective in killing bacteria over a wide pH range (pH 6 to 10) and under high temperatures, at a usage level of 150 to 200 ppm.

One advantage to using QUATS is that they are odorless, unlike chlorine and iodine sanitizers. Also unlike chlorine and iodine sanitizers under similar pH conditions, they are noncorrosive. Disadvantages with QUATS are they are sensitive to hard water conditions, they have poor efficacy at low temperatures, and they are ineffective against spores and may support the growth of pseudomonas (spoilage bacteria). QUATS generally are two to four times more expensive than chlorine disinfectants.

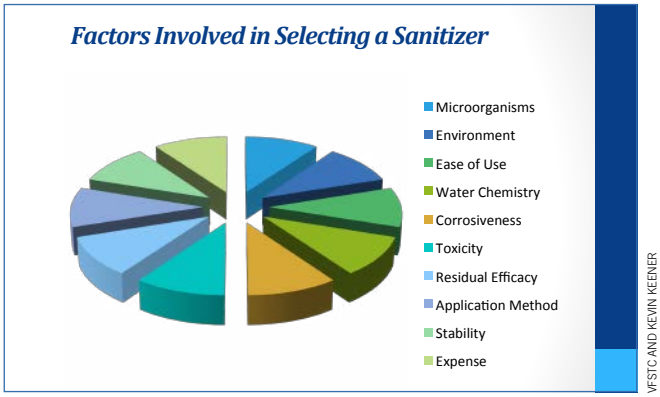
Peroxide. Peroxyacetic acid (PAA) has become a popular sanitizer in the food industry. This sanitizer has an effective usage level between 100 to 250 ppm. Advantages are that this sanitizer generates little foam and is effective against a broad microbial spectrum, including bacteria, yeasts, and molds. In addition, PAA is fast-acting and pH tolerant. It is also effective over a wide range of temperatures and under hard water conditions, as well as being nonreactive with organic soils such as fats and proteins. It is environmentally friendly and breaks down into acetic acid (vinegar), oxygen, and water. The disadvantages are that PAA does have a strong odor and becomes ineffective above pH 8.0. PAA is three to five times more expensive than chlorine.

Which Disinfectant to Use

The Code of Federal Regulations (CFR) contains requirements for sanitizing different kinds of operations. For example, 21 CFR 129.80 (d) includes a number of sanitizer options for sanitizing bottled water operations. These are all disinfectants and meet sanitizing requirements. Many times the selection of a specific sanitizer is determined by water chemistry, costs, and operational activities. If steam is available, it is a very effective and low-cost sanitizer; when steam is not available because of equipment complexity or facility limitations, many other chemical alternatives exists.

The chemical alternative is generally selected to minimize the impact on product quality. For example, a bottled water plant one will typical use a 0.1 ppm ozonated water over a 50 ppm chlorine solution because the residue from a chlorine solution may impart an objectionable taste even at levels as low as 1 ppm. Some facilities find that alternating between two different disinfectant types (such as a chlorine and a QUATS) allows better control of spoilage organisms.

Environmental considerations may come into play when choosing a chemical disinfectant. Wastewater discharge requirements, the level of wastewater treatment capacity at the facility, pH, water temperature, and water chemistry management may factor into the decision.



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Deciding between so many possible disinfectants might seem difficult unless sanitation is your full-time job, but there are plenty of suppliers that can help you identify the right product type and the most appropriate level for your water type, pH, temperature, and equipment type.

Verification with ATP

After cleaning and sanitizing is complete, how do company personnel know equipment and other surfaces are indeed clean and sanitary? Verification is absolutely the most critical part of a sanitation plan and should never be skipped, no matter how small the operation. In fact, small operations are at higher risk for bacterial contamination of equipment, which can affect the product and be passed on to the consumer. A company can be ruined if a product is recalled or, worse yet, people get sick from a foodborne illness.

First, start with a visual inspection immediately after cleaning. Surface contamination must be removed along with the residual cleaner. Lighting in some facilities is not always optimal, so visual inspection should be performed with a flashlight, a spotlight, or even a black light. This serves as a daily "check."

Periodically, a rapid chemical test using adenosine triphosphate (ATP) bioluminescence should be performed to verify clean conditions prior to sanitizing. This commercially available rapid swab test measures the amount of organic matter remaining on a surface by detecting the amount of ATP in the organic matter. ATP is a vital energy source that microbes easily store and utilize for cellular functions. The amount of ATP—and where it is located—alerts company personnel to possible trouble spots that might need to be re-sanitized before starting the next production cycle.

Once the testing swab has been swiped across the surface of interest, the swab is placed in a solution and undergoes a reaction, producing light. The swab is then placed in a luminometer, which measures the light intensity produced in "relative light units" (RLUs). The light intensity is directly related to the amount of ATP on the surface, and therefore is an indicator of the amount of organic matter remaining on the surface. High remaining organic residual levels may render a sanitizer ineffective.

How often to do ATP testing? That depends on a lot of factors. Depending on the size of an operation, a company might have 50 different sampling sites and test five of them a week.

Microbial Assays. ATP test results, however, do not correlate to microbial count. The high RLU might result from food residue, not from potentially harmful bacteria. For that reason, ATP test-

ing is complemented by conducting microbial testing on the surface and in the air and/or in the water rinsed through equipment, both before and after sanitizing. Microbial testing can determine what microorganisms are contaminating the production area, which can help identify the source.

A sanitizing solution consists of a chemical compound that is mixed with water and applied to a surface.

These microbial assays generally include testing for aerobic plate count, or APC, which indicates bacterial populations that grow and proliferate in the presence of oxygen (aerobic conditions) and in some instances, may involve more sophisticated testing for genus of bacteria which include potential pathogens such as *Listeria* spp. *Salmonella* spp., and/or *E.coli* spp. These microbial test methods utilize sterile agar plates, swab techniques, or petrifilm to verify the effectiveness of the sanitizing practices utilized in the food processing facility.

For a small operator, the prospect of utilizing microbial assays to verify the success of a sanitation program might seem intimidating and expensive, but do not hesitate to seek outside help. Once again, there are a number of chemical suppliers and related companies that provide service and assistance in establishing verification and validation programs, including testing and monitoring. Associations also have technical bulletins. The cost of a foodborne illness outbreak would undoubtedly cost more than hiring an outside lab. Again, there is a great deal of variation in how often a company carries out microbial assays to verify the efficacy of its sanitation program.

Remember, the new FSMA may mandate written hazard-control plans, and state departments may extend FSMA requirements even to smaller operators that FSMA exempts. Once a hazard-control plan is in place, you must have verification that it is working effectively. Utilization of visual, chemical, and microbial test methods enforce and ensure that proper sanitary practices are being carried out. The final key piece to any sanitation puzzle, of course, is employee training and implementation of proper sanitary procedures. Practicing all the measures in your plan on a continuous basis will validate the sanitation plan's efficiency and effectiveness in food processing facility. ■

Dr. Keener is a professor in the Department of Food Science at Purdue University and is a core faculty member with the VFSTC. This article was written with the assistance of Jacqueline Kochak, who is with the Auburn University Food Systems Institute, home of the VFSTC. Dr. Keener can be reached at kkeener@purdue.edu.

Safety & Sanitation

SANITARY EFFORTS

Eliminate Bugs Where They Live

Identifying the problem areas in the plant where microorganisms can find a home | BY **LORI VALIGRA**

Despite major advances in plant and equipment design aimed at minimizing places pathogenic and spoilage microorganisms can hide and breed, the sheer volume and speed of food production combined with the unpredictable element of human interactions still leaves room for improvement in reducing microbial presence. Stoking the push toward more effective sanitation is the forthcoming Food Safety Modernization Act (FSMA).

The current approaches being used are broad and include everything from automating sample data collection in order to identify trends and take predictive action, to minimizing potential contact surfaces in heavily used equipment, to improving the fundamentals like handwashing.

"It is a holistic approach that needs to be taken to monitor and control what is going on in plants," says Tom Dewey, global marketing manager, 3M Food Safety, St. Paul, Minn. "A key part is 'are we being effective.' A lot more attention is being paid to recalls now, and there are a lot better ways to test for and identify bugs than there were 10 years ago, as well as to identify problem areas of a plant."

Data Trending

Hazard Analysis and Critical Control Points (HACCP) standards are a key part of that process, combined with analyzing data from routine adenosine triphosphate (ATP) hygiene monitoring results and tests like chemical concentrations, pH, as well as time, temperature, and humidity measurements, according to Dewey. 3M's approach is a data trending system called Clean-Trace that can help identify pass, fail, and caution areas in the master sanitation schedule. Clean-Trace software also can analyze test results and provide reports about the cleanliness of a production line over a given time, identify which areas fail sanitation standards most frequently, and which could be hot spots, like high humidity plants where raw meat is turned into cooked meat or other criteria.

"We try to be predictive where we can," Dewey says. That includes monitoring the effectiveness of sanitizers. Some plants change out the wash chemicals because certain organisms become immune to them, he mentions. One example is a plant that makes dressings and sauces where chemicals are changed because the factory wants to assure the hard-to-reach areas are cleaned as effectively as possible. And while the evolution of the overall effectiveness of chemicals and sanitation has allowed that plant to reach 99.6 percent cleanliness, it still is striving to improve that number, Dewey says.

A lot of oversight is needed for certain industries, so the data collected daily can be used over time to map it to different crews and to look at the concentration of chemical sanitizers used. "Once you look at the data on a trend chart, you can see if you have issues with the weekend crew, for example, or an area where a specific piece of equipment is on the high end [toward possibly failing] but still passing. You can see problem areas," Dewey explains. For instance, an old piece of equipment that may have micro cracks on it that might foster the growth of microorganisms.

Some of this testing data still is collected by hand, and some of that is merely collected but not turned into information that can be used effectively, he says. The 3M system uses ATP through a consumable test and then a laminator to read the ATP. That data then is put into the master sanitation schedule.

Dewey says the information can be used effectively at audits and to help meet FSMA requirements. "Every piece of equipment cleaned needs to be signed off on by the people who cleaned it. They can't start up again unless all of it is done," he says, noting that some factories can have up to 90 individual sheets of paper printed every night from such testing. The testing also helps with hazard analysis and methodology for managing an adverse event.

"What we're identifying is the importance of a complete system that provides accurate results to be verified by the customer and has a fast time-to-result," he says. "Accuracy is most important factor. An Achilles heel can be a moving target in some plants, while others stay awake at night because they can't find a problem."

Eliminating the Cracks

One approach to minimizing bacteria and other organisms is to limit the places

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they can hide. This involves designing conveyor belts, drums, and other pieces of equipment and components that have fewer exposed surfaces, and in some cases, that use smoother metal.

Conveyors in the past were built in such a way that they had many areas where food could catch or water might pool, for example on belts and motors, notes Jim Monaweck, project manager at Walker Custom Sheet Metal in Grand Rapids, Mich. Monaweck, a 40-year veteran in the food processing business, began working on a sanitary and tool-less conveyor about five years ago, and the company has been marketing it for about a year. Monaweck says it can be snapped apart quickly and has fewer exposed parts to accumulate food and germs.

He says conveyors years ago were cleaned with air and then washdowns with hot water and chemicals became popular. Recently, foaming agents were added to the mix. The equipment was then swabbed to see if there were leftover microorganisms. "In the past a lot of sanitation departments would go in and look with flashlights to see if they were clean, but conveyors are dark [areas] that could be harborages," he says. "They can be an area where food gets trapped or falls off." The way to get to the hard-to-reach areas is to take them apart completely, but that has been a cumbersome and slow process requiring a mechanic and downtime for the line personnel.

Monaweck figured out a design that he says is quick and easy to disassemble. "It's designed so every part can be taken off, leaving a frame that is open for sanitation and inspection," he says. The company's product, called the W.O.W. (Walker Original Washdown) Conveyor, can be taken apart in minutes versus hours. Machines can be cleaned daily or even several times a day. According to Monaweck, the other advantage is that disassembly doesn't require the plant mechanic; a regular line worker can take it apart.

While he notes that his company's conveyor can cost around 15 percent more than conventional conveyors, he says there are savings in sanitation, maintenance, and downtime as well as in the amount of sanitizing chemicals used.

One company that benefited from the improved conveyor system is El Matador, a Michigan-based corn tortilla chip maker. The company states the tool-less conveyor helped it quadruple output while keeping safe sanitation standards.

Bill Stanley, El Matador's maintenance manager, says in a write-up about his company's application that the sanitation team performs all of the conveyor disassembly and reassembly in less than 10 minutes compared with 30 minutes for previous conveyors. The company's sanitation manager, Bill Mourer, adds there also is an overall reduction in food safety risk because it's easier to remove the belts. The machine has an open, cantilever style and it's easier to clean areas around bear-

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ings and pulley shafts that the company couldn't clean before.

Monaweck says the equipment design helps reduce plants' risks to pathogens. It also can help with factories that run allergen and non-allergen food on the same conveyor. "Plants are trying to get ahead of FSMA to prevent issues in the future. They need to pay attention to design and have a greater degree of cleanliness," he says.

Another area of focus on all types of equipment, including conveyors, is metal finishes. Some metals have microbial coatings. Others have finishes, like the No. 4 stainless steel finish that has short, parallel finishing lines and "looks pretty." But Monaweck contends that those lines are like scratches that microbes can attach to. "We don't use it on food-contact surfaces," he says. "I think in the 21st century we will get away from finishes like No. 4 on the food-contact surface because of the chance of microbes attaching to the finish." Microbes are less likely to attach to a mirror finish, but he says that's too expensive to use in the food industry, so there are other smooth finishing alternatives.

Monaweck notes that part of his work is to educate clients about what surfaces work best for their applications. Since more companies are cutting their engineering staff in recent years, it's more important than ever to educate those staff members who have taken on new responsibilities when it comes to plant sanitation.

Keeping Components Clean

Rollers and drum motors are components of conveyors that also have drawn attention as areas for new hygienic designs. For example, Interroll, a Wilmington, N.C., maker of conveyor rollers and drum motors, has a drum motor design in which the motor, gearbox, and bearings are internal to the tube, improving its hygienic value, comments Tom Dickinson, product manager. He says the company's products, known as AC Drum motors, have an Ingress Protection Rating of IP-66, meaning they can be washed down at high pressure and protect against particles. In addition, lubrication is done internally using food-grade oil that he says is approved by the FDA.

According to Dickinson, there's anecdotal information from customers who feel the press-on fit stainless end caps, stainless drum, and stainless surface help eliminate crevices where bacteria can build, and are quicker to clean. "Some believe the reduced bacteria makes the conveyor a more hygienic design, thus reducing the chances of recall due to bacteria spreading on food being conveyed," he notes. He says the average price of a recall is $20 million to $30 million, so the penalty for not minimizing bacteria is high.

Interroll's drum motor design can be washed down at high pressure and can protect against particles.

"The challenges have to deal with the spread of bacteria and the methods in washing down a conveyor or system," Dickinson points out. "Bacteria travel with water." Interroll motors, he says, have fewer crevices for food to get trapped compared to external gear motors, and if food does get stuck, it can be washed away more easily. Both the end cap that holds the drum motor in place and the drum motor itself were designed with hygiene in mind, he says.

And like the Walker Custom conveyor belt, the Interroll drum motor can be cleaned in less time, in this case one third of the time, so there's a production cost savings, Dickinson says. Stopping a line for cleaning can mean $60,000 to $70,000 per minute in production, he notes. "Even a fraction of a minute is a big deal."

Jake Hughes, sales manager for Omega Metalcraft Inc., Suffolk, Va., who is a customer of Interroll, says the internal nature of the drum motor is good for his end users. He builds conveyers for the ready-to-eat environment. "Most conveyors in the field use ball bearings that require grease," he explains. "But these [Interroll] have a motor and gear box that are sealed, so there's no harborage points and nothing is exposed to the elements." According to Hughes, most *Listeria* is found in food-grade grease that is used to lubricate bearings, and some plants have grease systems that self-lubricate the bearings. He says a prominent poultry processor based in North Carolina uses the sealed drum motors to avoid such grease problems, which have been tied to recalls in the past. The drums, he notes, eliminate most of the crevices and harboring points.

Handwashing Remains Key

While computer and software tools to identify and monitor problem areas and new types of conveyors and other equipment with fewer areas for microorganisms are among the innovative techniques food processors are focusing on to improve sanitation, at times it's the least common denominator that remains a sticking point, in this case, compliance with proper handwashing methods. Cascades Tissue Group of Waterford, N.Y., is among the companies working to get employees' hands cleaner both for their own sake and for the safety of the food and equipment they're handling.

Cascades came up with antibacterial towels that don't require any changes in routine. "Five seconds with the towels is better than washing hands and air drying," says Andrew Sheridan, product manager, quoting a University of Westminster study that found air dryers can increase the bacteria count on hands up to 254 percent, whereas paper towels reduced it up to 75 percent.

He says if someone doesn't wash their hands fully, the dry paper towels, impregnated with benzalkonium chloride, will kill bacteria.

The towels fit in traditional multifold or universal roll containers already in restrooms and near food machines, he says. They also come in a popup box. They run about 15 percent to 20 percent more costly than standard towels, but there are savings when bacteria is kept from spreading to cause a product recall or employee illness.

These towels are only for hands, not surfaces. Sheridan says the antibacterial action in the towels has shown a persistent effect, continuing to kill bacteria even after a person has dried their hands with them. He adds that his company will look for ways to improve the towels, such as adding other ingredients to kill other types of microorganisms. For more information on hand hygiene, see "Handwashing's Risks and Rewards," p. 44. ■

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

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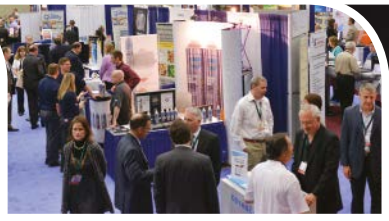


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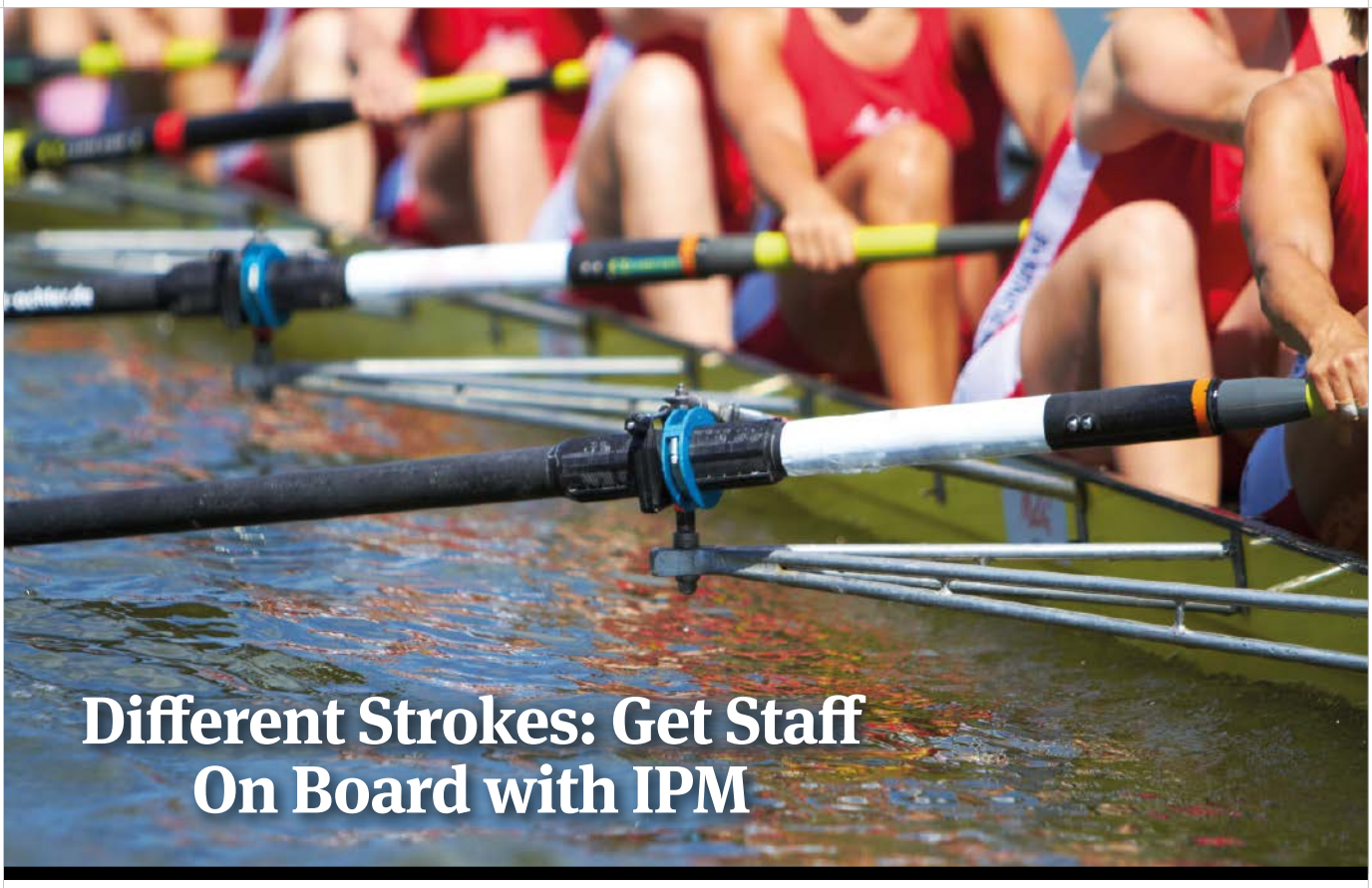

Different Strokes: Get Staff On Board with IPM

Teaching staff how they can play a role in pest control adds more value to your management program

BY **ZIA SIDDIQI, PHD, BCE**

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

Food processing plants—large and small—are hard to run on your own. But you don't have to be alone in the fight against pests.

Consider soliciting help from staff members to help facilitate your facility's pest management program. After all, more eyes looking out for pests will increase the likelihood of spotting a problem before an infestation sets in. Beyond reporting pest activity, your staff can actually play a role in the pest management program itself once they understand how their day-to-day responsibilities can help support your overall Integrated Pest Management (IPM) program. This will push your facility even closer to the goal of IPM: Preventing pest activity proactively, rather than reactively, by promoting regular facility maintenance and stringent sanitation to diminish the food, water, and shelter pests need to survive.

To teach staff about pest management and get them on board with your facility's pest management program, keep the following five steps in mind.

1. Take every chance to learn. Pest management is an ongoing cycle of activities that includes continuous monitoring and periodic reevaluation of the facility's program. This means that, as pest activity changes, there is a chance for you and your staff to learn the science behind pests and the treatment options that can help manage the problem. But before going that far in-depth, learning the basics is essential. Ask your pest management professional to provide onsite IPM training for staff to ensure they understand the importance of proactive pest prevention. In addition, request your pest management professional provide educational materials like tip sheets that employees can refer to after the training session. Professional associations, such as the International Association for Food Protection and International HACCP Alliance, may also be able to share educational resources if the pest management professional is not capable of doing so. Don't forget to teach staff about the signs of pest activity you look for every day—such as droppings, gnaw marks, and rub marks—so they can play a part in catching pest issues at the start.

2. Establish a focus on "hot spots." Each food manufacturing facility has pest "hot spots," which are internal and external areas that both provide conducive conditions and are prone to pest activity. Hot spots for food processing facilities often include floor drains, loading docks, and food storage areas. Exterior walls with even the thinnest of cracks and crevices pose a threat to the building, as pests

like cockroaches need just 1/16 of an inch to crawl into the facility. Request staff members keep a close eye on their surroundings so they can help point out any and all sanitation and maintenance issues that may give pests an "in" to the building. If any issues are identified, work with your pest management professional to resolve the problem through exclusion techniques, a stringent sanitation program, and pest treatment when needed.

3. Assign a role to each of the staff members. An exemplary pest management program has many components to help keep pests away from your property and products. Although it may seem that weaving IPM into the staff's daily responsibilities will cause confusion, many hands can actually make for light work when it comes to pest management. Keep the complication to a minimum with staff by giving just one or two responsibilities to each person. Further, consider making those responsibilities align with the daily tasks each staff member executes, ensuring the pest prevention responsibilities are within their comfort zone. At the same time you assign the responsibilities to staff members, also make sure to explain who they should notify if a pest issue arises.

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More eyes looking out for pests will increase the likelihood of spotting a problem before an infestation sets in.

4. Communicate well and frequently. Once everyone begins to play their assigned role in the facility's pest management program, be sure to establish open lines of communication from you to your staff to your pest management professional. Without effective, frequent communication, discrepancies may begin to develop in your program—which can ultimately lead your facility to a reactive approach to pest issues, rather than a proactive one. By building a positive relationship between your staff and your pest management professional, you'll continue reaping the benefits of your IPM program in the long run.

5. Handle each situation by following pest sighting protocol. Although you may have followed the first four steps to a "T," there's always a possibility pest activity will set in at the facility. Since all hands are on deck, it's important to set a pest sighting protocol to guarantee everyone at the facility knows how to communicate pest activity to both you and your pest management professional.

- Request that at least one of the pests—whether insects or rodents—be caught and provided to the pest management professional for positive identification. Information on where and when the pest was seen should be shared as well.
- Let the pest management professional take the time to properly identify the insect based on its biology, behavior, and appearance. This will ensure that proper treatment methods can be recommended for your facility.
- Help the pest management professional determine where the entry point for the insect lies in order to prevent further pest penetration.

If the mentioned five steps are enforced with staff, you will see an added value to your pest management program that may not have existed before. Remember to always take the time to teach staff so everyone can enjoy the benefits of minimal to no pest activity at your facility. ■

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

Rapid Detection's Role in Marine Food

Using tests based on lateral flow technology to detect the increased instances of *Vibrio parahaemolyticus*

BY **LISA JOHN, JÖRG SLAGHUIS,** AND **HEIKE WULFF**

Traditional microbiological methods for detection of pathogens in food can require up to five days to obtain a simple yes/no result. This time-consuming process slows the workflow, holding the food in quarantine and preventing its release. It can then result in a considerable delay before products can be put into the market. Immunoassays based on the principle of lateral flow technology allow for convenient detection of pathogens within 24 to 48 hours, depending on parameter. These tests are available for a broad range of pathogens and follow a simple "pregnancy test" design to provide results in a quick, readable format and deliver definite results in as little as 20 minutes after sample enrichment.

Lateral flow tests offer all the benefits of traditional testing methods with the addition of simplicity, speed, reliability, and convenience. When used as part of a monitoring program, they allow streamlining of testing protocols, ensuring the safety of finished products and shortening holding times. Lateral flow tests are currently available for:

- *Bacillus cereus*—Enterotoxins and emetic toxin,
- *Campylobacter*,
- *E. coli* O157,
- STEC/EHEC— Verotoxins (Shiga toxins 1 and 2),
- *Legionella/Legionella pneumophila*,
- *Listeria monocytogenes* and *Listeria Genus*, and
- *Salmonella*.

This article describes development and evaluation of a lateral flow test for pathogenic *Vibrio parahaemolyticus*, a major cause of foodborne illness throughout the world, primarily associated with consumption of contaminated raw or undercooked seafood. (Note the lateral flow test for *V. parahaemolyticus* is not commercially available.)

Background

Approximately 4,500 cases of *V. parahaemolyticus* infection are reported each year in the U.S. Numbers are expected to increase worldwide due to greater consumption of raw seafood and the globalization of seafood trade.

Thermostable direct hemolysin (TDH) toxin is known as the major virulence factor of *V. parahaemolyticus*. Standard detection methods of *Vibrio parahaemolyticus* vary by country, but all are labor-intensive and require three to seven days for results. Because raw seafood quickly experiences deterioration, rapid detection methods are necessary for effective identification of possible contamination.

For this application, a Gold Labeled ImmunoSorbent Assay (GLISA), an immunochromatographic rapid test based on lateral flow technology (Figure 1, p. 32), was used. The lateral flow assay (LFA) detects the toxin TDH using monoclonal gold-labeled antibodies. If the antigen is present, it reacts with the gold-labeled toxin-specific antibodies and migrates to the binding zone. The gold-labeled toxin-specific antibodies then link to a second specific antibody. Due to the gold-labeling, a distinct red line is formed. The rest of the sample continues to migrate to the control zone and links to a third antibody-specific antibody. The red line formed in the control zone demonstrates that the test is functioning correctly.

Methods

Three studies were performed to evaluate the assay for TDH toxin:

- Limit of detection,
- Inclusivity/exclusivity, and
- Evaluation with artificially contaminated food samples.

To establish the limit of detection, four different TDH positive strains of *V. parahaemolyticus* pure cultures were diluted and tested with the LFA. Pure TDH was also tested.

Inclusivity and exclusivity of the LFA were evaluated by testing a total of 102 isolates and reference strains. Bacteria were cultured in Peptone water (acc. to ISO 6579) plus 2 percent sodium chloride pH 8.5 or in CASO Broth for 18 to 24 hours at 37 degrees Celcius. A total of 160 microliters (µL) of suspension was transferred onto the sample port of the test device. The result was read after 30 minutes.

For evaluation with artificially contaminated food samples, fish and seafood products (oysters, shrimp, and sushi, n=90 total) were spiked with a TDH-positive *V. parahaemolyticus* strain and analyzed comparatively by the developed test and the reference method according to ISO/TS 21872-1:2007 (Figure 2, p. 32). For inoculation, stressed and non-stressed cultures were used. Samples were enriched directly following inoculation or after storage for seven days at -20 degrees Celcius. Enrichments were incubated for eight hours and 24 hours. Centrifugation of the sample was evaluated as a pre-sample treatment for performance improvement; 160 µL of sample was transferred to the LFA. The result was read after 30 minutes.

> Because raw seafood quickly experiences deterioration, rapid detection methods are necessary for effective identification of possible contamination.

Results

The detection limit of TDH was 125 picograms (pg)/mililiter (ml) and 3.3 x 10^6 to 1.9 x 10^7 colony forming unit (cfu)/ml for TDH-positive *V. parahaemolyticus*, strain-dependent. The LFA achieves an

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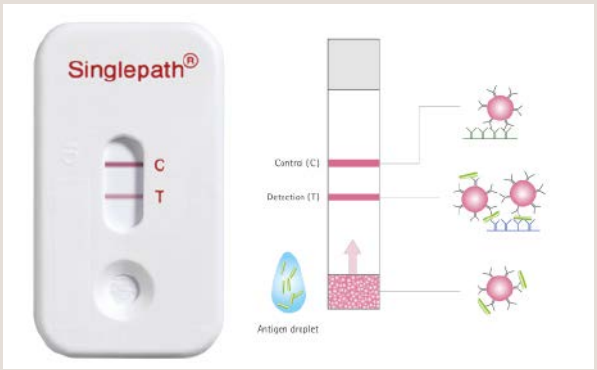

Figure 1: Principle of Lateral Flow Tests.

Species		n	Result LFA	Inclusivity/ Exclusivity
V. parahaemolyticus	*tdh*-gene positive	n = 21	n = 17 positive	Inclusivity 81 %
	tdh-gene negative	n = 69	n = 69 negative	Exclusivity 100 %
other *Vibrio* spp.	*V. hollisae* ATCC 33564 *V. cholerae* Eltor Ogawa NIH 41 *V. vulnificus* ATCC 27562 *V. vulnificus* ATCC 33149 *V. mimicus* ATCC 33653 *V. alginolyticus* H6533	n = 6	n = 6 negative	Exclusivity 100 %
non-*Vibrio*	*E. coli* ATCC 25922 *C. freundii* ATCC 8090 *A. hydrophila* ATCC 7966 *P. shigelloides* ATCC 14029	n = 4	n = 4 negative	Exclusivity 100 %

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Figure 3: Results of inclusivity and exclusivity testing.

(Continued from p. 31)

inclusivity rate of 81 percent and exclusivity rate of 100 percent. For the inclusivity six *tdh*-gene positive *V. parahaemolyticus* isolates were tested negative by LFA (Figure 3). They are of environmental origin (e.g. seawater and zooplankton) and were tested for TDH production by Latex agglutination test KAP-RPLA (Denka Seiken, Japan). Two of them showed no agglutination (TDH negative) and therefore were excluded in the LFA inclusivity rate calculation.

For fresh food, detection rate of the LFA after 24 hour incubation, in combination with no centrifugation step, was significantly lower than the rate obtained by other methods. In the group of frozen samples, detection after 24 hour enrichment (independent from centrifugation step) was significantly higher than after eight hour enrichment.

For both fresh and frozen food types, 100 percent sensitivity was achieved by LFA after 24 hour enrichment in combination with sample centrifugation. Performance was equivalent to the ISO/TS 21872-1:2007 reference method (100 percent sensitivity) and time-to-result was achieved four days faster. The preliminary centrifugation treatment of the sample significantly increases the detection rate (p=0.035). None of the negative controls were contaminated with TDH-positive *V. parahaemolyticus*, but sporadically with TDH-negative *V. parahaemolyticus*. All negative controls reacted negatively by LFA. Therefore, the specificity of the LFA was 100 percent.

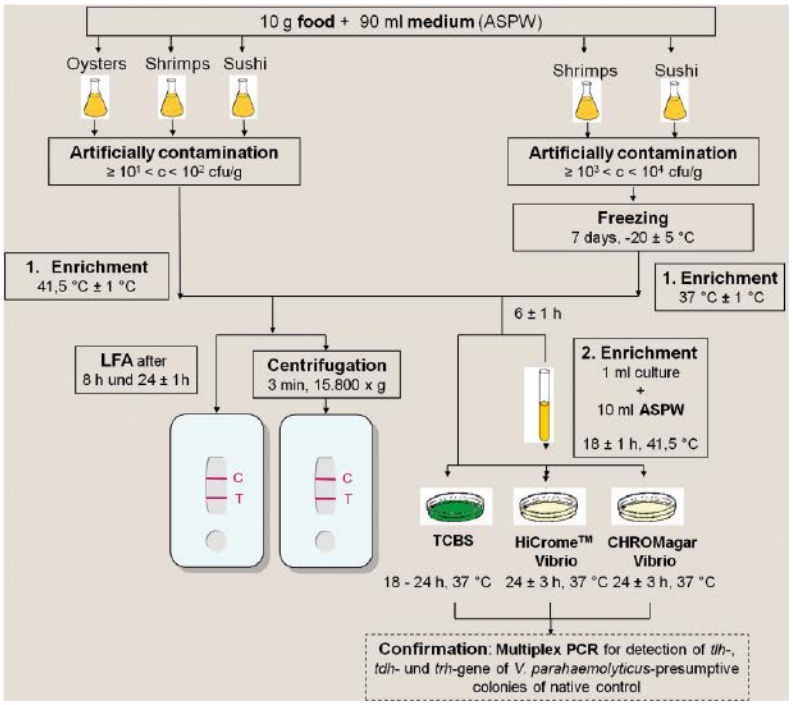

Figure 2: Test procedure of food experiments. Comparison of LFA method ISO/TS 21872-1:2007.

Conclusion

Food experiments with artificially contaminated seafood samples showed that TDH-positive *V. parahaemolyticus* was reliably detected in inoculation concentrations of 10^1 to 10^2 cfu/gram in fresh food and 10^3 to 10^4 cfu/gram in frozen food after 24 hour incubation.

A GLISA for the detection of pathogenic *V. parahaemolyticus* in food was developed by targeting the toxin TDH. The detection limit of TDH was 125 pg/ml and 3.3 x 10^6 to 1.9 x 10^7 cfu/ml for TDH-positive *V. parahaemolyticus*. In internal studies (n=102), a sensitivity of 81 percent and specificity of 100 percent was determined for the developed test.

Experiments show that *V. parahaemolyticus* in seafood can be detected much faster using lateral flow technology than with traditional methods. Detection was completed in 24 hours with enrichment plus one hour sample pretreatment and assay performance compared to three to seven days for standard detection methods. ■

John, Slaghuis, and **Wulff** all work in the area of biomonitoring research and development at Merck Millipore in Darmstadt, Germany. John is manager of immunological microbiology group; Slaghuis is director, head of research and development biomonitoring; and Dr. Wulff is a research scientist in immunological microbiology. Reach them at heike.wulff@merckgroup.com.

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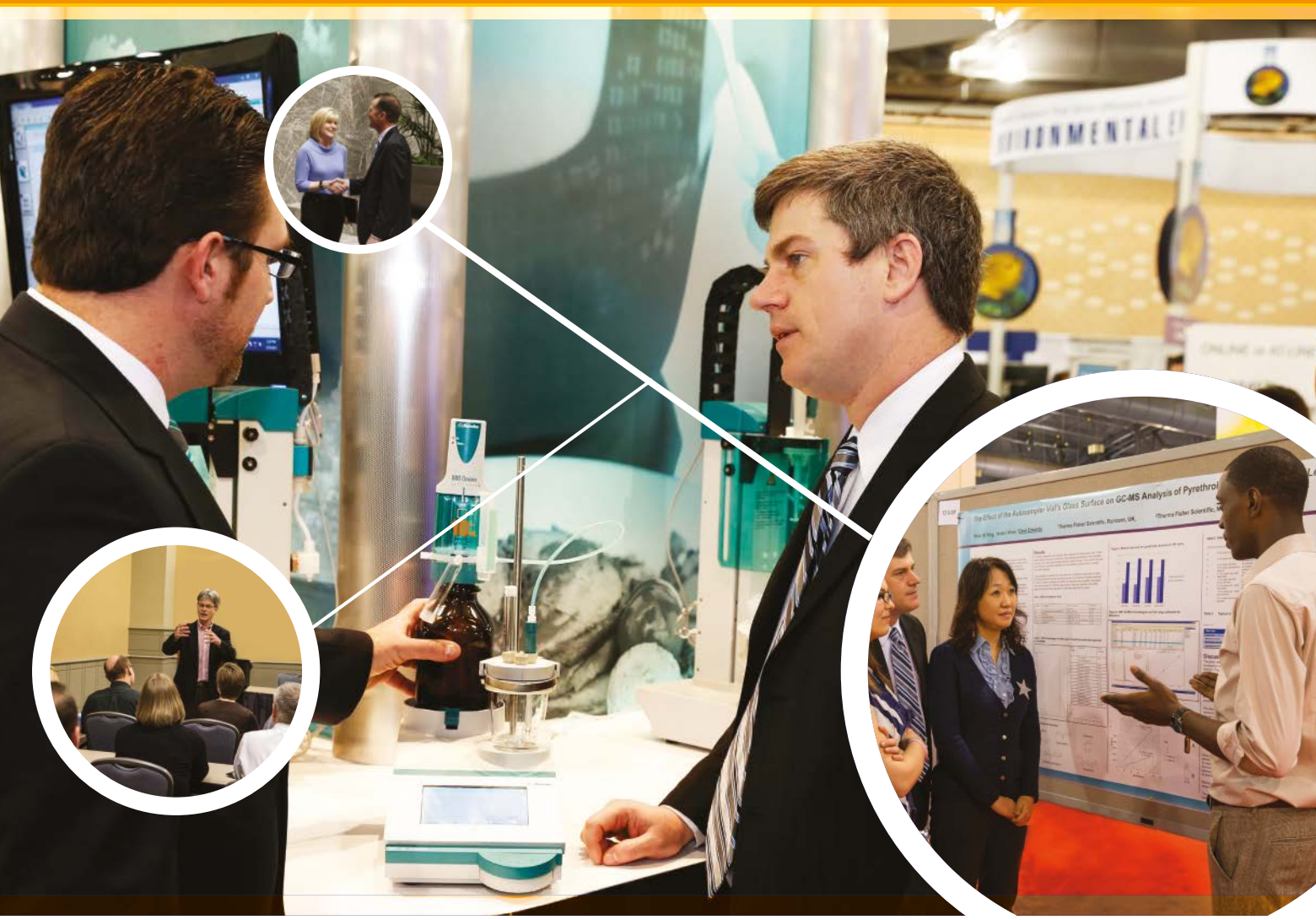

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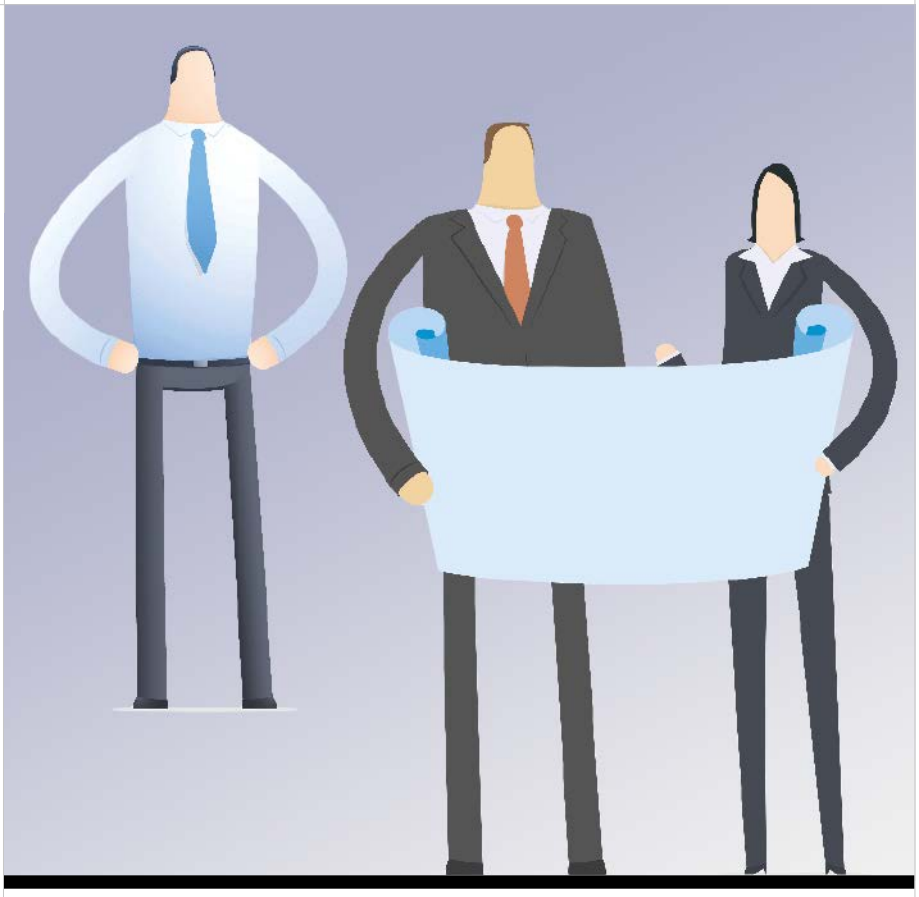

Third-Party Auditors Rule: Are You Left Out of the Reporting Loop?

In addition to direct reporting, the FDA's proposed rule would require auditors to report to the FDA ***before*** they report to the facilities

BY **PATRICIA A. WESTER**

Like many, I have spent a great deal of time reviewing the recently published proposed rule on Accreditation of Third-Party Auditors/Certification Bodies. There are many interesting provisions warranting in-depth review and discussion, but none raise the amount and degree of concerns as the provision requiring third-party auditor/audit agents to directly report certain findings to their certification body (CB), that the CB report them directly to FDA, and do so *prior* to reporting them to the audited firm. This information reporting loop is the focus of this discussion.

It's not clear what additional information would be available by having the auditor and CB bypass the facilities in the reporting process. From a practical perspective, I'm not sure it's even possible to prevent them from obtaining this knowledge; they are involved in the audit, accompany the auditor throughout the audit, and auditors are instructed to inform plant personnel of nonconformities as they occur. How can they not know something serious has been observed?

If the Food Safety Modernization Act (FSMA) originally intended to give the FDA an opportunity to leverage the sheer quantity of data available in these audit reports, all would agree that still makes sense in today's economic environment. However, there now appears to be a shift to expecting "too much (from) of a good thing" as the proposed rules attempt to define how that process should look. Actually, the phrase appearing most often when discussing this rule is "unintended consequences."

FSMA defined two types of audits, regulatory and consultative. The intent appeared to be that in separating them, industry would still be allowed to use consultative audits as a learning tool without ramifications and little would be changed to alter the way they are executed and used.

It seemed only audits used for regulatory purposes (certifications, Foreign Supplier Verification Program, or Voluntary Qualified Importer Program) would carry any additional requirements such as those supported by the framework established in accreditation and certifications rules for ensuring validity of the data.

FDA has done an excellent job of outlining the requirements for a sound, robust accredited certification system in the proposed rule. There are however concerns with the direct reporting component that may negate the good. In fact, we now see that not only will there be direct reporting requirements for both types of audits, those requirements actually exclude the audited site until after FDA has been notified.

If those asserting the number of audits will drop off based on these direct reporting requirements are correct, what does

that mean in real numbers? In 2011/12, there were an estimated 35,000 plus audits executed globally against various Global Food Safety Initiative (GFSI) schemes. For arguments sake, let's assume each audit had a mix of minor and major nonconformities, to make the math easy we'll use 10 per audit. Theoretically, that's 350,000 corrective actions completed in a 12 month period that otherwise may not have been addressed. Do the benefits of reporting "immediately" to FDA truly outweigh the potential loss of future improvements? Let's look at examples of direct reporting to find out.

An auditor was auditing a facility that produces processed fruit products. He was accompanied by the plant manager and the sanitation and quality assurance manager—both of whom were recently hired and unfamiliar with the auditing process. The audit was a certification audit, so in proposed rule terms it would be considered a regulatory audit.

During the audit, multiple flies/insects on raw materials and product contact surfaces were observed. The apparent "violation" is certainly one that meets the basic public health risk threshold and is clearly outlined in FDA's *Compliance Policy Guide* as to the exact number and location of insects necessary to be adulterated. This also meets the criteria for a critical violation that would result in the suspension or denial of the sites' certification in GFSI schemes.

Serious Violations Must be Authenticated

When a potential critical nonconformity is observed by an auditor performing a regulatory/certification audit, he should have internal technical support to ensure the finding is accurate and contains the complete facts of the situation. He should not be alone in making such a key decision—a meeting with all stakeholders during the audit is often used to address this need.

In our example, the CB and the auditor reviewed the entire process flow and determined the area of the insect activity was the initial preparation step of the raw fruit in a separate, isolated area designed for that purpose. The plant manager explained how the fruit was subjected to a series of rigorous washing and sorting steps in an adjacent facility and this was observed by the auditor to be well cleaned before beginning the heat processing. All agreed the washing/sorting process was

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> The phrase appearing most often when discussing this rule is "unintended consequences."

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adequate to control insect contamination and there was no critical nonconformity.

During this process, the plant still has Reportable Food Registry (RFR) obligations that are now complicated by the auditor/CB reporting process. For example, the RFR only gives the facility 24 hours to evaluate and report, so what is its responsibility here? Should it wait until the CB completes the review and officially reports to FDA, then file RFR? Suppose the CB doesn't complete the review in time? Is it in fact faced with violating RFR obligations by the new reporting requirement?

Thankfully, this case happened before the proposed rules were published. The CB had a standard procedure to follow that included review of all relevant facts and the plants' input on process and procedures. The audit was completed and certification was granted. Had the initial finding been correct, FDA would know when certification was suspended or denied. Would anyone, FDA included, have been better served by reporting incomplete or incorrect information to FDA before notifying the plant personnel as would be required in the proposed rule? The answer is no.

If this had been a consultative audit, the auditor should observe and document how the plant handles the situation. Does it identify affected product and isolate it promptly? Are procedures followed for correcting this situation? Are the corrections adequate to prevent the situation from happening again? Does it accurately determine if product is potentially in commerce, which would need to be removed and reported? If necessary, does it file an RFR in a timely manner?

Now it would also require the auditor/auditing company to report to FDA. But the consultative auditing company may not have any review procedures. The proposed rule isn't clear on what the requirements are, if any, for an unaccredited auditor/auditing agent performing a consultative audit, so in reality this could be just one auditor acting alone. If so, is she obligated to report?

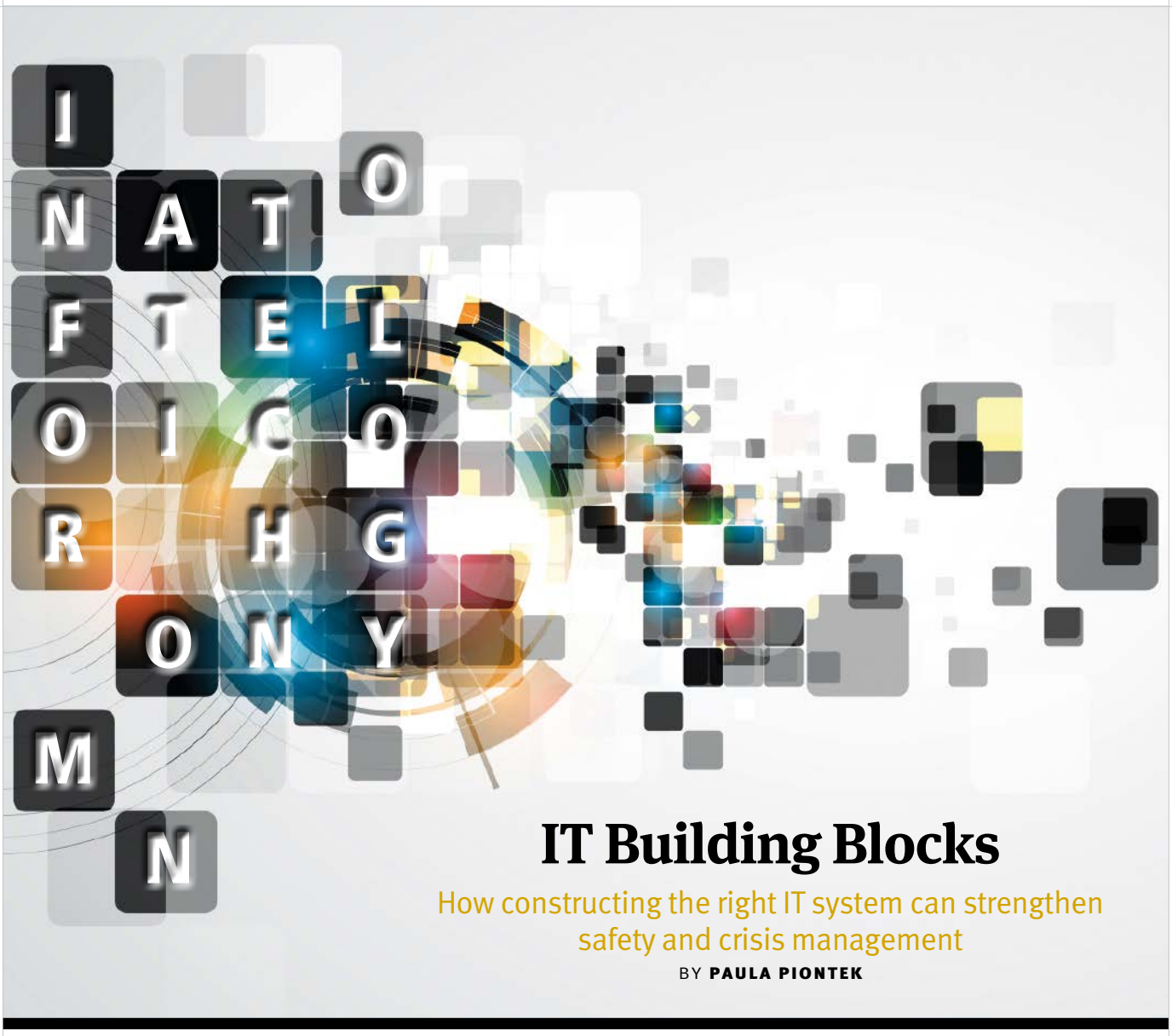
For arguments sake, let's say this is simply one individual, so the auditor stops the audit and files the report to FDA, letting the plant know afterwards what has been reported. After all, a statement that insects were observed on raw materials and product is serious and should be acted on promptly, right? Wrong! The finding was never reviewed prior to finalizing and reporting and the plant didn't have a chance to explain its processes. The auditor alleging the violation may/may not have the training or experience sufficient to make this decision alone. Ultimately, the finding would be proven to be incorrect, but the legal and liability issues would be messy to say the least.

Unless every auditor/audit agent performing consultative audits are operating under all of the accreditation requirements, their findings and auditing methods are not validated and should not form the basis of any official reports to FDA. There is no value in directly reporting information that is incomplete or has not been vetted.

What if, during this consultative audit, the plant simply refused to file the RFR report? This may be the only situation where direct reporting has value to all stakeholders. Reporting directly to FDA if a plant refuses to could be an incentive for the plant to follow the RFR requirements. But it's the only one.

Auditors audit and most do it very well. They are not enforcers though, nor are they quasi inspectors or even consultants. And they do not act alone. There is an entire cast of staff at an accredited certification body who provide experience and support to the auditor on the ground. Auditors should not be expected to make serious judgments without the input of these support systems. Let the RFR and consultants play their role, and accredited certification auditors theirs. And allow that system, with all of its checks and balances, to work before requiring any reporting. ■

Wester is president of PA Wester Consulting. Reach her at trish@pawesta.com.



IT Building Blocks

How constructing the right IT system can strengthen safety and crisis management

BY **PAULA PIONTEK**

Having a crisis management plan assures your company protects its consumers, your company's reputation, and brand, and avoids or minimizes financial implications in event a crisis were to occur. Every minute counts and how you respond to a crisis is critical to the outcome. Possible issues to a professional crisis response are lack of time to prepare, over or under reaction, multiple stakeholders, potential conflicts of interest, and media attention. With time being of the essence when investigating a potential recall, having the right technology is key to gathering pertinent facts to aid with the decision making process of a recall or crisis.

Communication

Designing the IT system to support the relevant business information your company needs is important. Records of supplier conformance may include specifications, lot coding details, certificates of analysis, quality testing, third-party audits, certificates of insurance, and supplier compliance or performance history. These programs require ongoing updates to assure records are current. Some IT systems have the capability to notify suppliers when key documents are expired or missing, allowing more time for quality

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or supply chain professionals to perform other key duties. This can also assure a company that with time differences across the globe, relevant information is shared instantly. As food companies rely on a global supply chain, it is more efficient to communicate relevant information as it may relate to a product recall or withdrawal utilizing a system of this design. These systems provide a documented notification time, persons notified, response time, person responding, or other designed records related to a product recall or withdrawal via email, text message, and phone messaging.

Identifying those who have not responded can be escalated to company management for follow up as necessary to maintain rapid communications and responses. It is especially helpful to have reports that can be produced to share with regulators as part of a company's crisis management program. These documents are critical when determining how effectively the company has responded to the crisis. Knowing who, when, and how the communications take place in real time are vital to company viability.

Trending

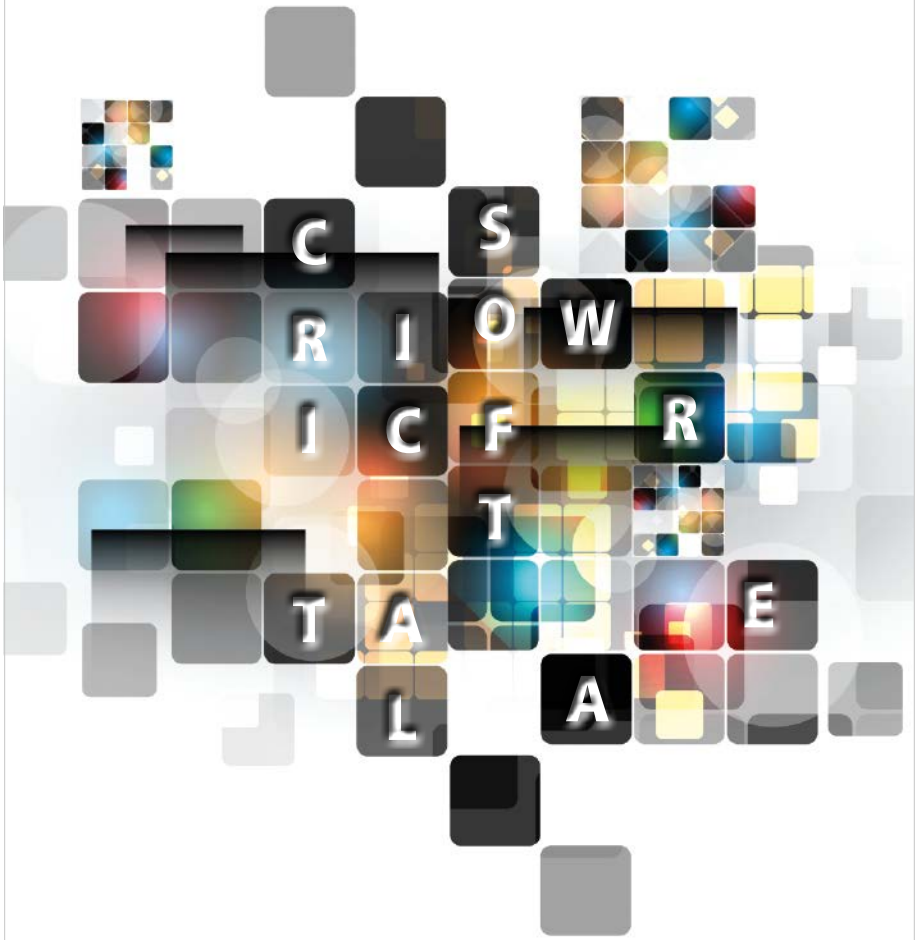
Many companies use trend reports for monitoring customer and consumer complaints. Having established trigger points designed into the system allows for escalation of serious food safety issues to be sent to a predetermined group and senior management. In conducting a root cause analysis investigation to an upward trend in complaints, review of internal production records, and maintenance schedules is necessary to determine if the company has identified the root cause and taken necessary corrective actions to prevent them from occurring again. If the company has appropriate IT systems, this information can be made available in minutes. When a delay in getting to these records occurs, companies may see escalation from an issue that can be handled and contained to a crisis.

The Supplier

A company needs to also consider its supplier history and trends when designing an IT system. Having the ability to monitor supplier performance can provide insight to a potential issue and prevent it from entering the company's production system. The system should include a sampling and testing plan for materials as they are received into the warehouse. Hold control programs for products pending test results and product noncompliance should also be included in the system. No products ought to be released until all testing has been completed and verified to be compliant. Companies that still ship product pending test results or that do not require testing prior to shipment can cause a major issue if the lab results indicate a problem and the product in question has been used upstream in the supply chain. Having a properly designed IT system will provide visibility to test results, pending tests, and controls for a good hold and release program.

In designing an IT system, the company must determine the scope of product involved with lot size or batches for finished products. It is beneficial to minimize the scope of product for each batch or lot by having a method to segregate and distinguish products in commerce. The system should account for incoming materials including packaging. An ability to cross-reference the supplier's lot numbers in the system is a necessity. It should have capabilities to account for samples of research and development, sales, shelf life, retained production, rework, employee sales, donations, and the company store. The system should define

Having the right technology is key to gathering pertinent facts to aid with the decision making process of a recall or crisis.



The system should include a sampling and testing plan for materials as they are received into the warehouse.

the lot start and end point, most likely correlating with a sanitation cycle.

Accuracy

Time is not the only factor in the crisis management process; accuracy of the information provided is instrumental to making decisions as it relates to the safety of the products in commerce. The company must consider impact to its brand if it cannot provide a confident scope of implicated products for its customers in a short period of time. For instance, if a company believes the product in question is one code date or lot, but later finds it had rework used on other code dates or lots, it must then make a notification that it has expanded the recall. Having clear and concise messaging for the distribution channels and consumers is key to getting a resolution, terminating the recall and preventing it from becoming a crisis. This means less production interruptions and a better chance of maintaining consumer confidence in the company brand.

Knowing the company lot coding system is an important validation within your IT system. Many companies manufacture products over a 24 hour time period. Decisions need to be made to determine if the day or lot code changes at midnight or at the next shift. This means the company has to validate that all records and systems are in sync with the determined lot change period. Not doing this can create uncertainty of the lots in commerce if trying to resolve customer complaints or tracing products related to an alleged issue.

In my experience, I have encountered a supplier that reported having a single day code of recalled product. When reviewing the records, it was found that the lot in question had been produced after midnight and marked with a new day code. The company needed to report this added day code to its distribution chain as this code needed to be traced and recalled. It was then determined the suspect product had been used as rework in other products. The scope of the recall went from one single product with a single lot code to a large variety of products with multiple day codes affected within 24 hours. The delay in getting this recalled from the start of the process allowed more affected products to be consumed resulting with a greater food safety risk. Needless to say, many long days and nights were spent trying to reconcile the recalled items. The company brand reputation was affected but did recover. Recovery of brand reputation can take time and affect the viability of the business.

Response Factors

When dealing with a crisis, a company needs to consider a reaction based on the available information and develop an immediate response. Factors to consider include the following.

- Are consumers at risk?
- Is the cause of the problem known?
- Is the lot number and product identified?
- Are there samples available for testing?
- Where has the issue taken place?
- Are the affected products within company control?
- How much was produced?
- When was it produced?
- Where did the product ship?
- Who received these products?
- How much did they receive?
- Do they still have the product?

Being prepared and testing your crisis management program provides your company with valuable insight to possible gaps in your plan and IT systems. Many companies perform product traceability exercises but do not go through a full scenario, testing their crisis plan to include senior management decision making and forming their response to the scenario. Taking time now to review these programs will provide more assurance that your company's programs are strong. If there comes a time when the programs are needed, your company will have a better chance of a positive outcome if the crisis is handled correctly.

Assess your supply chain management system to determine if it has what is required to support key decisions needed for a crisis response. By verifying the accuracy and timeliness of your crisis response program, you will be confident that your time and money are well spent to protect your consumers and the company brand. ■

Piontek is executive vice president-the Americas, product safety and recall, for red24assist, which provides crisis management assistance services in relation to food quality, product recalls, malicious tampering, and extortion. Reach her at paulapiontek@red24.com.

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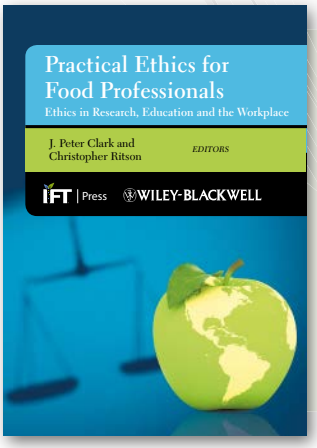

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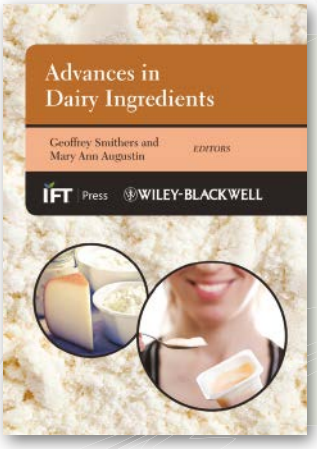

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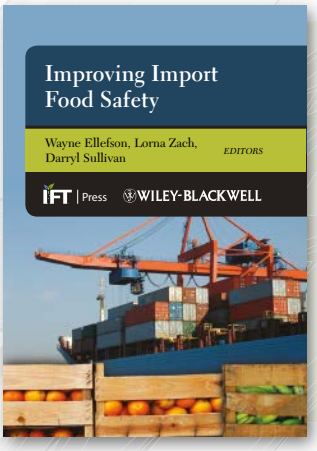

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Top Five Software Capabilities in Safety

Incorporate critical software abilities that leverage real-time, actionable knowledge and provide analytics for better control and consistency during production | BY **KATIE MOORE**

We've all seen the various headlines: "Contaminated peanut butter." "Metal fragments in cereal." "*Salmonella* found in eggs and tomatoes." "Mislabeled allergens."

Food safety concerns continue to be at the forefront of public attention, leading to high-profile product recalls. In today's age of supply chain globalization, ever-increasing consumer awareness, and evolving government regulations, there is a legitimate urgency among manufacturers to take more ownership of food safety to protect consumers and their brands.

The best way to optimize quality and minimize risk for prevention is through fully-integrated, end-to-end software capabilities. Forward-looking manufacturers that develop and implement integrated strategies with the right technologies can consistently deliver high-quality products, which in turn, drive productivity and efficiency improvements.

Prevention is the Goal

Until recently, most food manufacturers tried to minimize impact by reacting quickly. Common strategies in place were trying to identify and isolate tainted products through traceability to avoid any further potential harm to consumers, and

(Continued on p. 42)

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(Continued from p. 41)

damage control to minimize lost profitability and negative publicity. Now, as an industry, we have recognized the need to take a more proactive approach to food safety and efforts are under way. However, those efforts need to be fortified.

While response and communications to recalls are still critical, the shift now must be toward proactivity—preventing recalls and building in safety upfront before products reach consumers.

Government regulatory agencies and retailers worldwide are placing a higher priority on preventative strategies. They are strengthening requirements, improving processing practices, and escalating quality initiatives. This requires an integrated plan that drives more control across production and fosters closer collaboration between key stakeholders in the food industry: Suppliers, producers, regulators, academia, and consumers.

Manufacturers who incorporate real-time operational intelligence capabilities can gain the deep insights needed across to predict when problems are likely to occur and take real-time, corrective action. If they can stop a problem before it starts, they not only ensure consistent quality and food safety, but they also are able to be more productive and efficient—a critical advantage to stay ahead in today's highly competitive environment.

Critical Software Capabilities

1. Anywhere, anytime decision making. In today's mobile environment, it's imperative to deliver relevant information and notifications to operators and other key decisions makers wherever they are and through whatever mobile devices, such as smartphones and tablets, that they are using. Being able to respond quickly to critical events—minimizes the risk of safety mishaps while increasing productivity.

> The best way to optimize quality and minimize risk for prevention is through fully-integrated, end-to-end software capabilities.

Tools that give these mobile decisions makers contextualized information, based on their role and location for better, faster decision making, address the challenge of deriving meaning from the myriad of data available in today's operations while improving the way people work today, which is largely untethered.

Access to real-time and geo-intelligent information leverages proven mobile technologies to flexibly empower decision makers. For example, an operator walking in the plant gets notified of an event critical to his role, such as an out-of-spec incoming raw material, a quality sample lab result that has failed, or a metal detector check that is due. The operator can take immediate action and prevent the issue from escalating or being missed altogether.

2. Trending helps eliminate the root cause of product risk. The key to preventing recalls is the ability to proactively recognize production trends as they happen and take immediate corrective action as needed. It requires a shift from looking solely at historical data to connecting it to real-time production information.

Software with sophisticated trending capabilities can identify trends and deliver detailed insight into plant operations, including root-cause relationships. This allows quality improvements that will mitigate risks as they arise. Measured against food safety metrics, trending with real-time notifications of process upsets can help manufacturers identify and address small issues before they escalate into bigger problems. Understanding patterns and relationships between various sets of data, such as temperatures, speeds, pH levels, and humidity, can help eliminate the true root cause of product risk versus the reactive approach of compartmentalizing potentially at-risk products using post-production testing. For example, one food manufacturer used trending data to discover that its oven temperatures were not consistently being met for its product, increasing product safety risk. This critical intelligence was surfaced during the process before it reached the failure limit. Operators took immediate corrective action and adjusted the ovens "on the fly" to compensate for the temperature drifts, mitigating risk and ensuring product safety.

3. Predictive analytics allow problems to be corrected before they occur.

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Technology is a critical enabler for tighter controls to help safeguard processes and prevent quality issues.

Real-time, predictive analytics are vital to understand what could happen, based on trends, or to foresee issues before an event occurs. Advanced software with predictive analytics may leverage robust modeling engines and multivariate analysis to preempt alarm and failure events based on historical models, enabling "active avoidance." This protects quality and food safety.

For instance, high pH readings in a key processing step can compromise product quality. If the pH level starts deviating toward a critical condition, predictive analytics software can determine that a critical condition is likely to occur by using a process model built on past scenarios and process data. This model can identify the causes for the pH deviation, alert the operator, and give him or her information to make the correct, immediate decision to adjust the process to prevent the critical condition. And the operator's actions can be captured to further enhance the process model.

A U.S. dairy company used predictive analytics software to reduce spoilage in its dry baby formula product. By looking at content moisture, dry time, and several other parameters, it could predict the moisture content of its product and reach the desired state faster and more successfully while providing more consistency for the parameters that reduce spoilage.

4. Standardized work processes minimize inconsistencies. The centerpiece of any good safety program is standardized operating procedures (SOPs), which help operators consistently adhere to recipes and comply with Hazard Analysis and Critical Control Points (HACCP). Workflow software enables manufacturers to digitize manual and automated work processes, replacing static paper trails or binders at an operator station. Addressing the need for better operator guidance, digitization helps them follow SOPs and instructions with greater precision and fewer errors.

Through validated entry, workflow software captures data for analysis and historical records. It can help automate and manage HACCP monitoring, integrating production work processes with real-time HACCP testing to enable faster response to compliance issues.

For example, workflow can help manage a HACCP plan by automatically triggering HACCP sampling based on production events or elapsed time. This gives operators work instructions that connect production actions with real-time quality data. Such capabilities enforce HACCP and other SOPs and mitigate risks for inconsistent actions that could lead to quality problems and recalls. Furthermore, workflow software with mobile alarm response management enables operators to automatically and dynamically respond to production problems and events while monitoring alarms and out-of-spec conditions from multiple systems. It can track HACCP data in real-time and automatically adjust work processes to meet specification requirements, improving production processes for increased food safety.

5. Traceability enables tighter controls across the supply chain. Many variables can affect the availability and reliability of data on the plant floor and throughout the supply chain, which can be difficult to track and trace. Traceability has often been applied solely to minimize the impact of recalls and aid customer complaint investigations, but using it to improve food safety can virtually prevent recalls.

Software that offers rich traceability capabilities can trace a product throughout every step of the manufacturing process, identifying its exact materials and quality characteristics. It allows the flow of the product to be controlled between equipment and managed in-process inventories with greater transparency, and, hence, mitigation of cross contamination between production orders.

This type of software can leverage raw material intelligence and integrate the data to trace complex batches, continuous processes, sub-processes, and components or by-products. The origin and destination of all incoming materials and outgoing finished goods are known, improving food safety. By tracing raw materials to finished product, tighter controls can be put into place to safeguard the supply chain.

For instance, a food producer in Europe used traceability to better understand the effect a raw material had on its product. Although the shipping temperature fell within the specification, traceability revealed that a variation in the shipping temperature of the raw material had an ill effect on its finished product. By focusing on this parameter and working with the raw material supplier, the producer was able to tighten controls and improve product safety.

The Power of Integration

With prevention as the goal, these five critical software capabilities discussed play a distinct role in minimizing food safety risk, becoming exponentially more powerful when all are leveraged. The use of these important technologies provides a more holistic view of the factors that impact food safety. They allow manufacturers to shift to that critical proactive mode, giving them the insight, consistency, and transparency needed to identify and address potential food safety issues while products are still within the factory walls.

Technology is a critical enabler for tighter controls to help safeguard processes and prevent quality issues—increasing consumer confidence and protecting the brand. ■

Moore is the global industry manager, food and beverage, at GE Intelligent Platforms. She can be reached at katie.moore@ge.com.

Handwashing's Risks and Rewards

The lack of standards and processes for hand hygiene complicates the effort to reduce the risk of foodborne illness in food service and retail | BY **JIM MANN**

During the 20 years following the watershed outbreak event at Jack In The Box in 1993, the industry learned a lot about hand hygiene, cross-contamination, and a new generation of pathogens.

The newcomer, *E. coli* 157:H7, got center stage as the country and the world watched this outbreak play out. It awakened the public as well as the industry that a foodborne illness is a lot more serious than a fleeting stomach ache.

Twenty years earlier the Norwalk virus grabbed the headlines for the first time. Since then, with its name shortened to norovirus, it has maintained the headlines by soaring to the top of the list of outbreak causing pathogens. It regularly sends cruise liners back to port, invades nursing homes, and shutters restaurants.

In 2009, the CDC launched NORS, a web-based system to collect foodborne outbreak information and CaliciNet, a network of labs to feed a national database.

The more that is learned the louder the cry for better handwashing, both in quality and frequency.

Norovirus serves well as a focal point in setting handwashing criteria in food service and retail establishments. It is one of the smallest of pathogens and among the leaders in virulence. If the hand hygiene process is effective in removing or killing this microorganism, it will be capable of handling all the other common hand contaminants.

No Standards. No Measurement.

The lack of hand hygiene standards blunts the development and implementation of enhanced hand hygiene tools. What is a clean hand? What is considered an effective handwash? Without definitions like these, product research and development is discouraged.

Obvious advancements like touch-free electronic faucets are slow to be picked up by operators where short-term cost and efficiency are measured factors in their success and handwashing isn't. The incentive to encourage more handwashing is lacking. Efficiency trumps handwashing.

Some water saving initiatives even collide with best practice handwashing. A faucet flow of 2.2 gallons per minute (gpm) is very effective in accelerating good cleaning and thorough rinsing. Without all the information, some operators install restrictors, some down to 1.0 gpm. Now the time-short worker, frustrated by the low flow, walks away with a minimum of rinsing. It is soap residues that are a major cause of dermatitis. One sure way to minimize handwashing is to have it seen as the reason for dry, cracked skin.

A reliable electronic faucet is the better answer for those seeking water savings. This touch-free option delivers water when you need it and the flow stops while scrubbing, saving nearly a gallon of water for a single 20 second wash.

The lack of numeric standards obscures the patterns predictive of a breakdown in the system. "Is our deli running

at a safe or risky level?" The sign on the restroom mirror to remind workers to wash their hands and the certifications for the persons-in-charge do little to alert the management that its handwash process is trending down and about to break. Their first indication may well be the calls from the hospital's emergency room.

No Process. No Process Control.

In most food service and retail food establishments, process is king. It alone controls the risk, with one exception. There is no process when it comes to handwashing. Attempts are made to train employees why, when, and how to wash their hands. Training is budgeted annually. The trainers are given everything they need but no standards and no method to monitor the process.

A CDC observational study in the *Journal of Food Protection* found that a food worker would have to wash 8.6 times per hour to be compliant with The Model Food Code. This challenges the FDA and industry as both agree this is likely never to be achieved. Is compliance really that bad or is the Food Code overestimating many risks?

Advances have been made in making it easier and more inviting to wash hands. Handsoap formulations have advanced to provide effective cleaning while using skin-safe ingredients. This, together with touch-free dispensers, encourages frequent use.

Better papers, dispensed by no-touch electronic dispensers, are ideal for handwashing, affording a measured degree of friction to actually complete the cleaning-drying process.

Value-engineering and "green" initiatives periodically compete with handwashing's best practice choices and they frequently win. This harkens back to the lack of standards. A purchasing agent may get rewarded based on finding a lower price for a 60 percent recycled paper. No one bothers to check that the new paper crumbles when wet and discourages handwashing.

The false-saving of air-dryers is witnessed regularly in food service and retail restrooms, the very restrooms used by the staff as well as the public. Both, along with the quality assurance department and the health inspector, prefer paper towel drying but are muzzled by either a "green" argument or over an unsightly presence of paper on the floor. If that decision maker could only see the pathogens marching out through the restroom door on the hands of the great unwashed.

Hospitals are no better than food service when it comes to handwashing but they do have a useful organizational tool to protect best practices—the Infection Control Committee. When changes are proposed to a process like handwashing, they must approve. Restaurants and retail would be well advised to consider a three member Handwash Process Control Committee, bringing quality assurance, operations, and risk management together to help control the risk.

> Norovirus serves well as a focal point in setting handwashing criteria in food service and retail establishments.

The nailbrush raises another controversy. It simply can be used to accelerate good cleansing, particularly around the nail bed. However, the health inspector may request that the brush be tethered and stored in a sanitizer solution. Technically this is a good idea but the difficulty in keeping the sanitizer level at an effective range without risking skin damage makes it a bad idea. This method deters nailbrush use and the grimy appearance of the tethered brush may discourage use of the handsink altogether.

Some operators use an easily cleaned, self-cleaning fused bristle nailbrush. It is simply recycled by running it through the dish machine, power soak, or microwave as it has no staples.

Expanding Role of Hand Sanitizers

Hand sanitizers are one of the most under-utilized interventions in restaurants, convenience stores, lodging, and supermarkets. When operators want to add a further level of confidence and safety, these alcohol based, code compliant formulations have many advantages based on their versatility and convenience.

They can be applied directly at the handsink following a thorough wash. With the soil removed, this category of germ killers is highly effective. It is true that there is a wide range of performance when dealing with killing norovirus. Christine Moe, PhD, at Emory University in a break-through study discovered that human norovirus is much harder to kill than its calicivirus

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surrogate. She also identified one particularly effective formulation, breaking the myth that alcohol hand sanitizers are ineffective with norovirus.

Norovirus enters restaurants and delis through the front door as well as the employee entrance. Once inside, they welcome new hosts, contaminate shared surfaces, and threaten the wellness of both customers and employees.

Washing with alcohol hand sanitizer when water is not readily available has proven to be as effective as soap-water handwashing when followed by a second application of the sanitizer.

Multi-unit operations often know what's best based on third-party research but can't implement because some of the inspectors across the country in over 3,000 jurisdictions are misinformed or waiting for formal codification. Thus the risk of

citations and attendant administrative costs protect the status quo. The cards are stacked against innovation.

The handsink itself is too often considered a commodity and selected on price alone. Soon after installation operators will be adding splash guards as the water stream hits the flat shallow bottom, another discouragement to frequent handwashing. Deep draw handsinks minimize the splash and completely evacuate, leaving no soapy contaminated residuals to grow bacteria. Best practice handsinks also have a bacteriostatic surface which not only arrests the growth of germs but makes the unit easy to clean and very attractive, inviting more frequent use.

Gloving Challenges

Proper gloving adds safety to the handwashing/hand hygiene process. The public is the primary driver of the need for gloves, particularly around sandwich making and other handling of ready-to-eat foods.

Proper gloving first means selecting the right glove for the task, the right size and from a reputable supplier whose quality control spans the Pacific. The temptation to treat gloves as a commodity is tempered by trials.

Tear strength, cut resistance, comfort, ease and speed of donning, and doffing all are important considerations. Changing gloves from task to task is the challenge. Getting employees to change gloves can be harder than achieving handwash compliance. The better the glove, the more likely a timely change.

> Value-engineering and "green" initiatives periodically compete with handwashing's best practice choices and they frequently win.

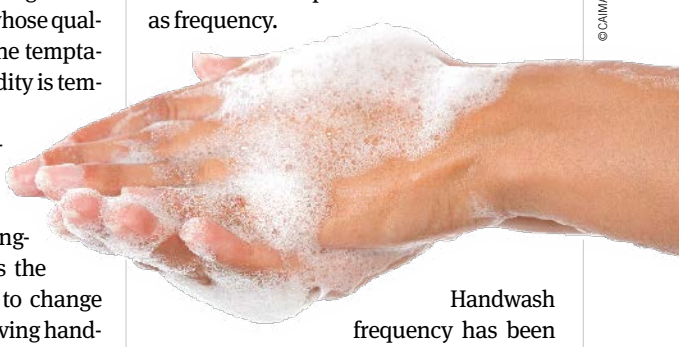
Infrequent glove changing is largely due to time constraints but the food codes and health inspectors provide another factor. If you are "caught" wearing a glove, clean or contaminated, you earn a positive checkmark. A bare hand earns you a citation from the inspector and a reprimand from your supervisor.

Rewarding Handwashing

Monitoring measured standards closes the risk-based loop of actions—Assess Risk, Set Standards, Optimize, Train, Monitor. Without it, training is largely wasted and the opportunity to motivate and reward is lost.

Monitoring the quality of the handwash is a key understanding set up in day-one training. Workers learn why and when to wash as well as it being a job-critical measured standard. This is best done by selecting a very personal and visual training option. For example, Handwashing For Life Institute's ProGrade system uses a UV traceable lotion so the trainee experiences what it takes to achieve the operator-set standard referred to as ServeReady Hands.

The quality of the wash is greatly affected by scrub time. Here a physical timer can help. Some electronic options will monitor elapsed wash time as well as frequency.



Handwash frequency has been largely limited to observation, a major contributing factor to low compliance. Technology assisted case studies commonly demonstrate a doubling of compliance rates when accompanied by a solid implementation process. Science is providing a growing bank of options, including video, infrared, radio frequency identification, and improved manual systems.

Finally, what about those frequently touched seldom cleaned surfaces? These are areas where bacteria can comfortably multiply and reach levels more likely to contain the pathogenic toxins. Setting effective protocols and monitoring results with reliable adenosine triphosphate system helps keep hands clean. Equipment quality, ease of use, and reliability are important characteristics. Without consistency and reliability, this method becomes a disappointing random number generator.

Away-from-home wellness is often in the hands of those serving the public when they dine. The CDC agrees and points out that "Handwashing is the single-most important means of preventing the spread of infection." ■

Mann is executive director at the Handwashing For Life Institute. Reach him at jmann@handwashingforlife.com.

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Spot-On Sanitation Methods

Providers are meeting the needs of the industry with innovative equipment, supplies, and services

By **Gina Shaw**

THE PROPOSED REGULATIONS IMPLEMENTING the Hazard Analysis and Risk-Based Preventive Controls portion of the Food Safety Modernization Act, issued earlier this year, have put a new spotlight on sanitation technology and services in the food industry. An increased level of inspections means more pressure on the sanitation side to up its game when it comes to systems, services, and supplies.

"It is absolutely crucial that food producers and manufacturers can measure the effectiveness of their cleaning and sanitation procedures," says Ben Pascal, CEO and cofounder of rapid-diagnostics company Invisible Sentinel, developer of the Veriflow molecular flow-based detection system. "ATP testing is quick and easy, but the best possible way to measure how clean things are is to do that from a microbiological standpoint that lets you know which pathogens are present and which aren't."

The responsibility for testing used to be up the line in quality assurance, says Jim Topper, market development manager for Neogen, whose Soleris microbial detection system added a 48-hour assay for *Alicyclobacillus* in August. "But lately we're seeing that the responsibility for doing the tests in the plant and making the determination of whether it's important to clean again or restart production has been more of a function of the sanitation group. For that reason, we've focused on ease of use with systems that allow you to make a decision right at the point where you need it–on the production line, where you often have 30 minutes or less between when production went down and the point when it's supposed to go back up."

Shifting from the testing side back to the actual sanitation equipment side, supplier Nelson-Jameson is urging a focus on safety with its Nilfisk certified explosion-proof and dust ignition-proof vacuums.

"Many in the manufacturing industry do not know what combustible dust is," says Devon Vogel, MRO product manager for Nelson-Jameson. "Unfortunately it can take a massive explosion, such as at the Imperial Sugar facility in 2008, to raise red flags and get the industry attention." The explosion at the Savannah plant killed 14 people and injured 38 more. In July, the federal U.S. Chemical Safety Board designated the issuance of a general industry combustible dust standard as its "Most Wanted Safety Improvement."

"It's important to know that traditional plant maintenance methods, such as sweeping and blowing down with compressed air, only make the situation worse by spreading the combustible dust around and making it airborne," comments Vogel. ■

Shaw is a writer for *Food Quality & Safety*'s eUpdate enewsletter. She also writes frequently about science, medicine, and health while serving as a regular contributor on notable medical publications.

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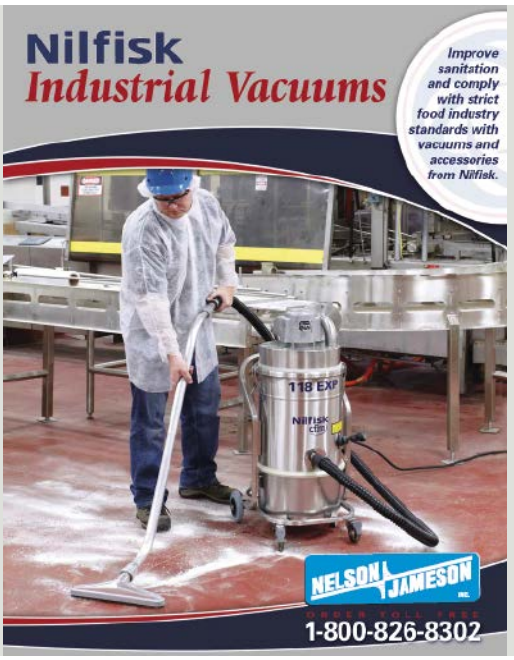

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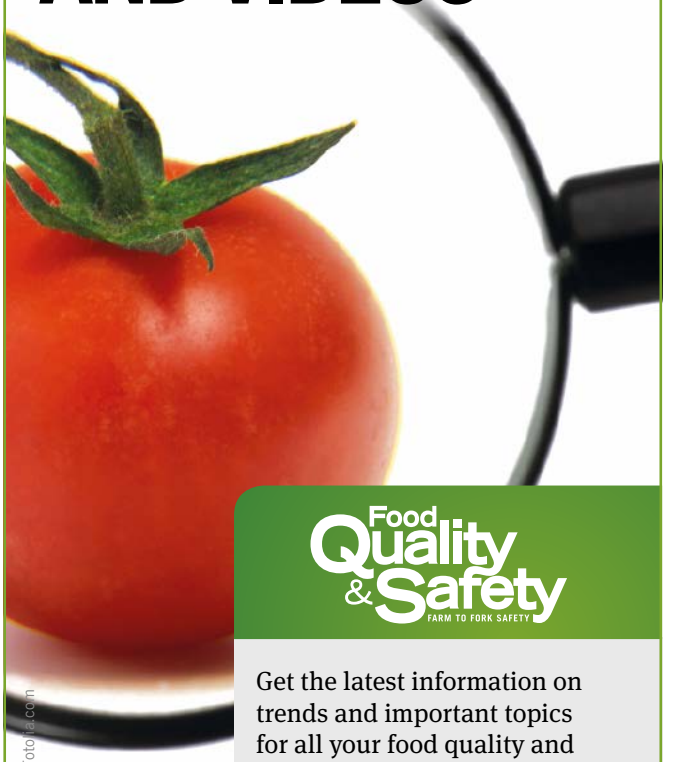

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Traceability Server

Information Repository & Intelligence Server (IRIS) is an event-driven traceability server that provides organizations complete visibility across the life cycle of a product. Combining Frequentz's data traceability technology with IBM's InfoSphere Traceability Server, IRIS can track, trace, and store all information around product development and supply chain logistics in a central, serialized data repository. Whether leveraging the technology for the purposes of gaining greater visibility, tracking food from farm-to-fork, or reducing risk of exposure, IRIS can provide real-time access to the complete life history and quality assurance of a product. **Frequentz, 650-397-2550, www.frequentz.com.**

Pathogen Detection Technology

The 3M Petrifilm *Salmonella* Express System, provides detection and biochemical confirmation of *Salmonella* in enriched food and food process environmental samples, including dairy, fruits and vegetables, raw meat, seafood, and pet food, and results are available in as little as 44 hours.

Also available is the 3M Molecular Detection Assay *Listeria monocytogenes*. This is the fourth test available for 3M Molecular Detection System, which provides simple testing for pathogens in a variety of food matrices. **3M Food Safety, 888-364-3577, www.3M.com/foodsafety.**

Detectable Brooms and Brushes

Made from Detectamet's plastic polymer, the range of brush products are completely detectable from the bristles to the top of the handles. The initial designs are made in food-contrast-blue with white handles. Options include choice of sweeping brush heads with an adjustable socket capable of holding handles from 18 mm to 25 mm in diameter. Various hand brushes are available for scrubbing surfaces, dishes, pots, containers, tubes, and bottles. **Detectamet Ltd., +44-(0)-1759-304-200, www.detectamet.co.uk.**

Onsite Animal Feed Analysis

The handheld microPHAZIR AG analyzer allows farm feed manufacturers to perform onsite analysis to test ingredients and finished feeds to optimize nutrient formulations. Designed to help identify out-of-specification ingredients before introducing them into the production process, the analyzer is pre-calibrated with INGOT calibration for feed ingredients—providing analysis of protein, moisture, oil, ash, fiber, starch, and other parameters as well. **Thermo Fisher Scientific Inc., 800-678-5599, www.thermoscientific.com/feed.**

Whole Room Sanitization

Advanced Oxidation System (AOS) Certified technology provides food and beverage producers with an environmentally sustainable system for controlling surface and airborne pathogens. Using ambient air to generate ozone and water to produce non-condensing humidity, AOS Certified technology fills the atmosphere with a sanitizing vapor that goes deep into every corner, rapidly penetrating hidden areas in equipment, drains, air conditioning vents, and fabrics. The vapor then fully dissipates, leaving no condensation or residue, making it effective even in dry environments. **Dow Microbial Control, 800-447-4369, www.dowmicrobialcontrol.com.**

Real-Time PCR Detection

The iQ-Check Prep automation system enables walk-away automation of DNA extraction and PCR plate setup. It runs up to four different iQ-Check assays simultaneously and performs 500 tests in one 8-hour shift. The system improves traceability with barcodes and LIMS integration; provides real-time monitoring of each pipet step with liquid level sensing; and uses internationally validated protocols. Air-displacement pipetting eliminates vacuum pumps and liquid waste.

In addition, Bio-Rad has released its KnowItAll Informatics System 2013 spectroscopy software, offering solutions for spectral analysis, identification, search, data management, and reporting. It supports multiple instrument vendor file formats and techniques. **Bio-Rad Laboratories, Inc. 510-724-7000, www.bio-rad.com.**

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Water Sorption

The new version of the Aquadyne DVS instrument measures the amount of water vapor a sample can adsorb and the rate at which it is adsorbed and desorbed. This is accomplished by gravimetrically monitoring the process while precisely controlling the amount of water in a flowing stream of nonreactive gas; a technique referred to as Dynamic Vapor Sorption (DVS). The instrument uses precision microbalances in a temperature-controlled housing, which enables the measurement of miniscule changes in weight in the microgram range. **Quantachrome Instruments 800-989-2476, www.quantachrome.com.**

Meat Species Identification

NeoSEEK meat species identification service detects adulteration at levels of 0.1 percent or 1 percent of mislabeled horse, pig, poultry, beef, or sheep meat. Precise quantitative results that show the percentage of adulterant in a meat sample are also available. Results are available within 48 hours of sample receipt at Neogen's facilities in Lincoln, Neb. Identification tests include F.A.S.T. (Food Analyte Screening Tests), which are immunostick assays that provide visual results in about 30 minutes. NeoSEEK utilizes a DNA-based assay featuring specialized PCR technology. **Neogen Corp., 800-234-5333, www.neogen.com.**

Cleaning Program

Advantis FC Cleaning Program is a high-foaming, chlorinated alkaline cleaner specially formulated for use with reduced temperature water. Advantis FC provides food and protein processing facilities with ideal cleaning performance against protein and fat soils on stainless steel processing equipment and plant environmental surfaces. It cleans protein and fat soils at temperatures as low as 105 degrees to 110 degrees Fahrenheit. The program improves cleaning performance in plants that cannot achieve or maintain high water temperatures throughout the sanitation shift. **Ecolab, 651-293-2233, www.ecolab.com.**

Microcentrifuges

The Microfuge 20 and 20R compact instruments meet the specific requirements of various research applications. Processes include nucleic acid and protein preparation; pelleting, extractions, purifications, concentrations, phase separations and receptor binding; and rapid sedimentation of protein precipitates, particulates, and cell debris. Allows entry and recall of up to 10 user-defined programs. Samples can be processed at speeds up to 15,000 rpm in the Microfuge 20 and in the 20R, a refrigerated version with a temperature range of -10 to 40 degrees Celsius. **Beckman Coulter Life Sciences, 800-742-2345, www.beckmancoulter.com.**

In Other Product News

Life Technologies Corp. partners with **PIKA Weihenstephan** to provide molecular testing solutions for detection of spoilage organisms in the brewing and beverage market.

Mérieux NutriSciences, through its Swift Silliker subsidiary, launches a new chemistry laboratory in Midrand, Johannesburg, South Africa.

Two rapid diagnostic tests from **Hygiena** for detecting coliform and *E. coli* receive Performance Tested Method Validation from AOAC Research Institute.

MODULAR's PlantFloorCertified program allows IT and plant management to select standard computing solutions for their plant floor—regardless of harsh-environment operating concerns.

Cherney Microbiological Services receives approval for accreditation by A2LA for its Cheese Proficiency Testing Program.

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Statement of Ownership

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Statement of Ownership, Management, and Circulation (Requester Publications Only)

1. Publication Title	2. Publication Number	3. Filing Date
Food Quality	0 1 5 _ 6 7 4	10/1/13
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price (If any)
Bi-monthly Feb/Mar,Apr/May, Jun/Jul, Aug/Sep, Oct/Nov, Dec/Jan	6	$152.00

7. Complete Mailing Address of Known Office of Publication *(Not printer) (Street, city, county, state, and ZIP+4®)*
Wiley Subscription Services, Inc. 111 River Street, Hoboken, NJ 07030
Contact Person: E. Schmidchen
Telephone *(Include area code)*: (201) 748-6346

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not printer)*
Wiley Subscription Services, Inc., 111 River Street, Hoboken, NJ 07030

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do not leave blank)*
Publisher *(Name and complete mailing address)*
Wiley Subscription Services, Inc., 111 River Street, Hoboken, NJ 07030

Editor *(Name and complete mailing address)*
Marian Zboraj, Wiley Subscription Services, Inc., 111 River Street, Hoboken, NJ 07030

Managing Editor *(Name and complete mailing address)*
None

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13. Publication Title	14. Issue Date for Circulation Data Below
Food Quality	August/September 2013

15. Extent and Nature of Circulation			Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies *(Net press run)*			20775	20615
b. Legitimate Paid and/or Requested Distribution *(By Mail and Outside the Mail)*	(1)	Outside County Paid/Requested Mail Subscriptions stated on PS Form 3541. *(Include direct written request from recipient, telemarketing, and internet requests from recipient, paid subscriptions including nominal rate subscriptions, employer requests, advertiser's proof copies, and exchange copies.)*	12799	12792
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c. Total Paid and/or Requested Circulation *(Sum of 15b (1), (2), (3), and (4))* ▶			12799	12792
d. Nonrequested Distribution *(By Mail and Outside the Mail)*	(1)	Outside County Nonrequested Copies Stated on PS Form 3541 *(include Sample copies, Requests Over 3 years old, Requests Induced by a Premium, Bulk Sales and Requests including Association Requests, Names obtained from Business Directories, Lists, and other sources)*	7150	6370
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e. Total Nonrequested Distribution *(Sum of 15d (1), (2), (3) and (4))*			7394	6580
f. Total Distribution *(Sum of 15c and e)* ▶			20193	19372
g. Copies not Distributed *(See Instructions to Publishers #4, (page #3))* ▶			582	1243
h. Total *(Sum of 15f and g)*			20775	20615
i. Percent Paid and/or Requested Circulation *(15c divided by f times 100)* ▶			63.68	66.03

16. ☐ **Total circulation includes electronic copies. Report circulation on PS Form 3526-X worksheet.**

17. Publication of Statement of Ownership for a Requester Publication is required and will be printed in the October/November 2013 issue of this publication.

18. Signature and Title of Editor, Publisher, Business Manager, or Owner
Elizabeth Konkle, Manager, Financial Planning & Analysis
Date: 10/1/13

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Innovators

IN FOOD QUALITY & SAFETY

Percy Spencer's Microwave Revolutionizes Fast Cooking

BY **LORI VALIGRA**

Like many food safety innovations, the microwave had its roots in a war-time effort, but in this case, it was radar devices to detect Nazi planes at night. British scientists had developed radar, which worked successfully to thwart raids, but they couldn't perfect a critical part known as a magnetron, which converts electrons into microwaves. They sought help from Raytheon Co., a U.S. military contractor, and more specifically, Percy LeBaron Spencer (1894-1970), a self-taught engineer who, with only a grade school education and creative thinking, promptly came up with a simpler manufacturing technique that also improved radar's performance.

Spencer first became interested in electricity at an early age. Born in the remote town of Howland, Maine, he worked in mills from the age of 12 and became intrigued by a local paper mill that was going to start using electricity, about which little was known in his hometown. He joined the U.S. Navy at age 18 and taught himself to become an expert in radio technology by reading textbooks during night watch duty. By 1939, he was one of the world's experts in radar tube design and was employed by Raytheon.

But Spencer's idea to apply microwave technology to cooking was more of a fortuitous coincidence. It occurred in the lull of business after World War II ended, when product development was shifting from military to civilian applications. While standing near a magnetron in a Raytheon laboratory in 1946, he noticed a tingling sensation. He also discovered that the candy bar in his pocket had melted. Others had noticed the same effects earlier, but Spencer's curiosity drove him to experiment, so he brought raw popcorn near the magnetron—it started popping. He built a simple metal box with a magnetron in it, which he tested to cook an egg and then used to reheat his lunches. Though rudimentary, it was the first microwave oven.

Spencer built the first true microwave oven by attaching a high-density electromagnetic field generator to an enclosed metal box. The magnetron device used for radar caused the stream of electrons interacting with a magnet to resonate in a high-powered vacuum tube, resulting in microwave radiation. In the case of the microwave oven, the magnetron emitted microwaves into a box, which blocked their escape and allowed for controlled experimentation. Spencer tested it further by placing various types of food in the box, observing the effects on it by the microwaves and monitoring temperatures.

Spenser wrote a report on his findings and Raytheon patented a high-frequency dielectric heating apparatus in 1946, after which it began selling microwave ovens for industrial use. The early models, available in 1954, were a far cry from today's compact and tastefully designed kitchen models: Each weighed in at more than 750 pounds, stood 5 feet 6 inches tall and cost upwards of $3,000. Initially the monstrous cooking machines were used in restaurants, railroad cars, and ocean liners, which needed to cook large quantities of food quickly.

But chefs soon noticed the oven's shortcomings, including turning some vegetables limp and colorless and not browning meats. After being refined for a couple decades, the microwave entered the homes of the average consumer, where it has become ubiquitous in the kitchen. The idea of rapid and safe cooking caught on and Raytheon's subsidiary, Amana, started selling the consumer Radarange countertop model in 1967 for about $495.

Microwaves have three characteristics that allow them to cook food: They are absorbed by foods, they are reflected by metal, and they pass through glass, paper, plastic, and similar materials. Microwaves reflected within the metal interior of the oven are absorbed by food, causing water molecules within the food to vibrate and produce heat, which in turn cooks the food. However, the microwave energy does contaminate or make the food radioactive because the microwave energy is changed to heat as the food absorbs it. Contrary to popular thinking, microwave ovens don't cook food from the inside out. Instead, the outer layers of thick food are cooked mostly by the microwaves, but the inside is cooked mainly by the conduction of heat from the hot outer layers.

The microwave oven has revolutionized consumer dining culture. In fact, more than five million microwave ovens are sold yearly in the U.S., according to market estimates, outselling range ovens since 1975. But Spencer's reward for his invention was small. He received a one-time $2 "gratuity" from Raytheon—at the time, the company paid all of its inventors on payroll for company patents. ■

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

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