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FOOD Quality

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THE BUSINESS OF RECALLS: FROM BOOMING TO BANKRUPT

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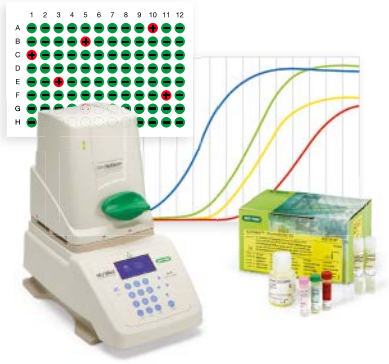

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The Business of Recalls: FROM BOOMING

Strategies on how to stay afloat amidst the growing frequency of food recalls

BY **NEIL CANAVAN**

Houston, we have a problem. Or maybe the problem is in Chicago, or Schenectady, or Cucamonga, or maybe all of the above. That's why when there's a food recall (the problem) the impact can be vast in scope, and astonishingly expensive.

According to the Centers for Disease Control, there are an estimated 300,000 hospitalizations and 5,000 deaths related to food-borne illnesses every year. The cost of these incidents to the economy is estimated to be $7 billion. Costs include notifying consumers, removing food from shelves, and paying damages that result from lawsuits. Further, short-term revenue is lost because of recalled/destroyed product, and in the long term, in some cases, the damage done to branded products may take years to repair. You may even go bankrupt, or out of business altogether.

A few recent examples:

2007: Canadian-based, Menu Foods, once the largest producer of pet foods in North America is held liable for the distribution of product tainted with the industrial chemical, melamine. The recall involved over 60 million units of pet food, at a cost of $42 million. An additional $24 was paid out in litigation. After share prices plummeted, the company was bought out.

2008: Westland/Hallmark Meat Packing Company is the subject of the largest meat recall in U.S. history. At the behest of the FDA, Westland/Hallmark recalled more than 143 million pounds of beef. Initial costs of the recall to the company exceeded $116 million. In November 2012, Westland/Hallmark reached a $500 million settlement with numerous plaintiffs, including the federal government. However, the assessment will go unpaid, as the California-based company is now bankrupt.

2009: In one of the deadliest cases of food contamination, a *Salmonella* outbreak occurred at a plant belonging to the Peanut Corporation of America (PCA). The outbreak resulted in more than 700 cases of serious illness and at least nine deaths. Days after a second plant was implicated in the contamination, PCA permanently discontinued operations. The economic impact of the recall extended far beyond PCA. The food giant, Kellogg, reported recall-related losses of $70 million, and Forward Foods, of Minden, Nevada, makers of the Detour brand energy bars, was forced to file for bankruptcy.

Recalls of this scale are uncommon, however, recalls in general, due to new regulations, heightened detection sensitivity, and the expansion of global supply chains are increasingly frequent.

In the third quarter of 2012, the FDA documented 414 recalls involving 189 companies, and 8.5 product units. That's 2.5 times the number of reported recalls for the second quarter, and the highest level recorded in more than two years. More than 55% of all units were part of Class I recalls, items which put consumers at the highest risk.

In 74% of the recalls the concern was *Salmonella*, *Listeria*, *E. coli*, and botulism contamination. Undeclared allergens or other allergen concerns account for the balance of recall incidents.

AVOIDING A RECALL

Nothing is foolproof, but there are steps to be taken to avoid a recall. Perhaps the most effective means is to create a culture of food safety within your company.

"We've seen much more awareness around the importance of employee training in the food industry of late," says Jeff Eastman, CEO of Alchemy, Austin, Texas. "I think people see it as more of a preventive control now rather than just regulatory compliance."

For the last nine years Alchemy has been designing and implementing food safety education programs that provide comprehensive and consistent employee training—consistent in that everyone, throughout the plant, or across multiple facilities is on the same procedural page.

Designed for production workers, Alchemy's SISTEM is a training and compliance management platform that enables food manufacturers and processors to train up to 150 employees with industry specific courseware that's updated regularly as laws, regulations, and industry best practices change. Using handheld remotes and interactive courseware, SISTEM validates employee comprehension, provides automatic documentation of results, and enables real-time reporting to quickly meet auditor requests.

TO BANKRUPT

The message is also skewed towards the personal, which can be a powerful tool. The training will incorporate familiar products—McDonalds, for instance—products that workers purchases themselves, and then using that association to drive home the message of food safety. "It's like, this is something you would feed your child," says Eastman. "How would you like that product to be handled?"

A platform like SISTEM also enables repetition. "You have to constantly train and reinforce the behavior if you expect that culture to be pervasive throughout your company."

"Most people do traceability today in what they call one up and one down look."

– PETER MEHRING, *CEO, Intelleflex*

Ensuring employees take part in a training program that advocates a food safety culture is a major factor in preventing a recall.

TAGGING ALONG

SISTEM allows you to follow the progress of an employee to help avoid any mishaps that might lead to a recall, while the ZEST cloud-based data collection platform, from Intelleflex, Santa Clara, Calif., allows you to track the journey of your product. The technology facilitates two critical aspects—the ability to verify the integrity of the cold chain; and the pinpoint location of product should there be need to pull it off the shelf.

"You can try traditional approaches, either through barcodes, or passive RFID (radio-frequency identification)," proclaims Intelleflex CEO, Peter Mehring, "but neither approach is very reliable." A barcode has to be manually entered at each station, and passive RFID doesn't work automatically around food of high water content, like produce. "People have to go after it with handhelds, so that's just like barcodes again..." Too much room for variability, for error.

The biggest challenge Mehring sees in recall events is location, location, location. "Most people do traceability today in what they call one up and one down look. They only know where they got it from, and where it went." To really figure out if your product's affected, you have to go through a chain of companies to get the data, and that can take days.

Intelleflex's solution is built around the hardware component (RFID tag) that travels with the product through the supply chain, with the tags checking in automatically at every access point. The data captured is then pushed to the cloud-based ZEST platform.

"Not only does ZEST capture that data, but we've built in a notification engine, based on business logic set up by the user, which notifies the given individual (via smartphone or PC) should an event occur." In other words, the information goes only to the person who needs to know it, say the person to remove a specific lot number from the shelf. The idea here is to manage by exception—meaning that the manager's attention should be directed exclusively to the thing gone awry, rather that on the mechanisms that are still humming smoothly along.

However, some potential customers have taken issue with the additional overhead. Mehring counters with this: Traceability is an excellent way to ensure freshness of product (saving money) while at the same time operating as a sort of insurance policy for optimum response should a recall be required. Sure, nobody wants to pay for insurance when they think they are great drivers, but as he sees it, particularly where leafy green produce is concerned, a recall is not a matter of if, it's when.

WHEN? THAT WOULD BE NOW

Precautions are not foolproof. Recalls do happen, and when they do, any future litigation may hinge on the manufacturer's appropriate, and above all, rapid response.

"A lot of companies do not possess the core capabilities to support recalls," says Jeri Cockrell, vice president of client strategy for Telerx, Horsham, Pa., "But we're equipped for an expedient response, setting up preferred channels of communication with a dedicated 800 number, social media contact, email, or even website support. Whatever modality is required."

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Once a recall is announced, a company like Telerx can be your point man in assessing the scope of the communication required, and addressing the concerns of your particular customer base. "We start asking questions of our clients immediately," says Cockrell. "We ascertain the household impact (a few hundred households, millions?), how many units of product are involved, is it a full product line, a specific lot number, is there a particular demographic that we need to focus on, be it children, or the elderly..." And then Telerx staffs accordingly. For instance, a high volume recall can have as many as many as 300 reps engaged one recall program.

"In some instances, the insurance companies will pay some, if not all of the cost of doing a mock recall."

– **BERNIE STEVES**, *managing director of Aon Risk Solutions*

It's also important to take into account the timing of a recall announcement. "If it's Friday at 5 p.m., generally you'll start seeing your volumes (customer queries) rising over the weekend, then Monday, the media pick it up, you get hit hard," notes Cockrell. A 1,000 percent increase in queries is not uncommon.

It's advantageous to be ready to handle the influx with as little as 24 hours notice. According to Cockrell, if the news breaks at 5 p.m., Telerx can be ready to answer customer questions by 8 a.m. the next day. Just five to 10 years ago you would merely set up an 800 number, says Cockrell, but today recalls are supported through chat, social media channels, phone, email, web support, etc. "There are so many different ways that consumers can reach you today."

The bottom line is that in order to protect your brand you have to get the information out there, and be able to address any customer concern in real time. Without those options to assuage fears, whom else might a customer turn to—a lawyer perhaps?

ENTER THE LAWYER

"We have worked closely with all segments of the industry in handling their regulatory crisis management and litigation in food safety," says Shawn Stevens, an attorney at Gass Weber Mullins, LLC, in Milwaukee.

If you have a recall that results in litigation, call an experienced attorney. Even before you're involved in a recall, it's a good idea to call an attorney with expertise in assessing client exposure.

"I'll come in and do brand protection audits for companies," comments Stevens. "I can look with a new set of eyes at problems that companies are missing. Sometimes it can be the most basic food safety procedures from an operational standpoint, something that with little or no money can be modified."

One of the major causes of bankruptcy can be inadequate coverage. "Any insurance policy can be tricky once you look at the fine print," explains Stevens. Many policies do not cover all the contingencies that a company might face during a recall.

Consider a market withdrawal: You've proactively invested it traceability technologies, pathogen detection systems, etc., and you caught a problem and traced it to the source before any outbreak occurred. You retrieved the lots in question and dodged a bullet. But it was expensive, yet, because no formal recall was executed, your recall insurance is not going to pay for a dime of the action taken. "So the company would almost be better off by ignoring the problem until someone gets sick—no company does that of course—but this (gap in coverage) is a huge problem," says Stevens.

Another scenario: Many policies are written to provide coverage only in the event of a government mandated recall. "The problem here is that every single recall in the history of recalls has been voluntary." The FDA, mentions Stevens, doesn't want to be in the position of overreacting, or misidentifying a recall culprit, so they pass the responsibility on to the corporate suspect. They will only strongly suggest to the company that a recall is in order. "So what will happen is these companies, as they always have, will announce a voluntary precautionary recall of their food products, so technically coverage would not be triggered under the policy."

GOING FOR BROKER

For a complete assessment of your recall insurance needs, call a broker.

Speaking from 25 years of experience, Bernie Steves, managing director of Aon Risk Solutions in Chicago, says it is not uncommon for companies to assume a recall is already covered by their product liability, or general liability policies, but that generally isn't the case. A broker can assess the recall-related utility of your existing policies and look at the food safety systems being employed (RFID, pathogen testing, training programs, etc.) to gain an overall picture of a company's risk; a broker asks upfront what the insurance underwriter is going to be asking later.

"We look at each insured a little bit different," says Steves. Are you a branded product? Are you a co-packer, or ingredient supplier, is your exposure more first party, or third party? And so on.

Should you purchase a recall policy, and you really should, there are perks you may not be aware of. "One of the most important aspects of these policies is that each of the insurance carriers has retained crisis consultants that are available to assist the insured in the event of an incident." These crisis consultants are available to assist in managing that situation, experts who have dealt with recalls and know how to effectively recall products, and how to properly get the message out.

"Most of the carriers will also make those consultants available before an incident happens," says Steves, "and in some instances, the insurance companies will pay some, if not all of the cost of doing a mock recall—bringing consultants in and practicing your recall plan."

Keep in mind that the insurers are there to help you because they don't want to pay for a recall any more than you do. It's their input that may make the difference between thriving, just surviving, or going under. ■

Canavan is a freelance writer based in Brooklyn, N.Y. Reach him at ncanavan@hotmail.com.

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FSMA Update

QUARTERLY UPDATE

New Proposed FSMA Regulations: From Farm to Fork

An overview of what exactly the two FSMA rules from the FDA mean for the food industry

BY **SARAH BREW** AND **COURTNEY LAWRENCE**

After much anticipation and delay, on January 4, 2013, the Food and Drug Administration (FDA) released two proposed regulations under the Food Safety Modernization Act (FSMA) that will have a significant impact on food growers and producers: 1) Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Human Food; and 2) Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption. The new rules are part of FDA's overarching efforts to shift food safety focus from reactive to preventive. FDA met with farmers, industry, consumer groups, the international community, and other key stakeholders to develop new regulations that are practical and not "one-size-fits all."

CGMP & Hazard Analysis & Risk-Based Preventive Controls

FDA's proposals would add a new set of regulations implementing the Hazard Analysis and Risk-Based Preventive Controls provision of the FSMA. The new

rules focus on preventing problems that can cause foodborne illness through two changes: Revisions to the existing CGMP and the addition of preventive controls.

Revisions to the CGMPs. The proposed rule would update or delete certain requirements in the existing CGMPs and generally "modernize" the language of the CGMPs. It would clarify that existing CGMP provisions requiring protection against contamination of food also require protection against cross-contact of food by allergens. Provisions directed to preventing contamination of food and food contact substances would also include preventing contamination of food packaging materials. Certain other CGMP provisions would be deleted, including provisions recommending temperatures for maintaining refrigerated, frozen, or hot foods. In addition, FDA is requesting comment on whether it should mandate training for food production facility employees and supervisors.

Preventive Controls. The proposed rule would require facilities of a certain size to develop formal, written food safety plans to prevent and correct food safety issues. Specifically, a facility would be required to evaluate "known or reasonably foreseeable" hazards; identify and implement preventive controls to address these hazards; monitor performance of the preventive controls; establish corrective action procedures when needed; and verify that the preventive controls are adequate to control the hazards identified. The preventive controls would include, as appropriate, process controls, allergen controls, sanitation controls, and a written recall plan. In all respects, FDA intends each facility's food safety plan to be tailored to fit the facility and the risks associated with the facility's food.

Food facilities are also required to document actions taken under the food safety plan, and those documents must be made promptly available to the FDA upon oral or written request (such as during an inspection), and to reanalyze the plan at least every three years. In addition, food facilities are required to appoint a "qualified individual" to prepare and oversee the food safety plan. The proposed preventive controls align with Hazard Analysis and Critical Control Points (HACCP) systems, but the new rule differs in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.

The tentative proposed rule does not include requirements that companies engage in either environmental monitoring or finished product testing. However, FDA continues to seek comments on these provisions, and FDA recently indicated such provisions would be in the final rule.

The tentative proposed rule does not include requirements that companies engage in either environmental monitoring or finished product testing.

In general, with some exceptions, the preventive control provisions would apply to facilities that manufacture, process, pack, or hold human food and are required to register with the FDA under Section 415 of the Federal Food, Drug and Cosmetic Act. Activities within the definition of "farm" would not be subject to the proposed preventive controls. The proposed rules provide exemptions for certain facilities and for certain activities. For example, very small facilities or activities subject to and in compliance with existing HACCP regulations for seafood and juice are exempt from the requirements for preventive controls. In addition, the FDA is proposing modified preventive control requirements in certain circumstances, such as modified requirements for warehouses solely engaged in the storage of packaged food that is not exposed to the environment. Modified requirements would also apply to "qualified facilities" (a very small business or one with three-year average annual sales of less than $500,000, with more than half of sales going directly to consumers or to restaurants/retail food establishments in the same state or within 275 miles).

Recognizing that smaller businesses may need more time to comply with the requirements, compliance dates would be phased in based on business size. "Very small businesses" that are not exempt would have three years to comply after publication of the final rule, "small businesses" would have two years to comply, and all other businesses would have one year to comply after publication of the final rule. To help the industry, particularly small and mid-sized businesses, comply with the new requirements, the FDA helped establish a Food Safety Preventive Controls Alliance to develop a core training curriculum and to disseminate information on hazards and controls.

Standards for the Growing, Harvesting, Packing and Holding of Produce

FDA's second set of proposed rules would establish minimum safety standards for the production and harvesting of fruits and vegetables on farms. The FDA's proposal builds upon prior produce safety activities by the FDA and the produce industry to establish standards and best practices, such as the Leafy Greens Marketing Agreements in California and Arizona and the Model Code for Produce Safety. In developing the rules, FDA considered both the commodity and the practices associated with growing, harvesting, packing and holding the produce as well as how produce will be used and consumed after it leaves the farm. The resulting rules are designed to allow growers flexibility in their approach to on-farm food safety, with the ability to implement food safety practices appropriate to the scale of production and type of agricultural practices used.

The rules focus on agricultural practices and propose new standards in working, training, and health and hygiene; agricultural water; biological soil amendments; animals in growing areas; equipment, tools, and buildings; and specific standards for sprouts. They cover most fruits and vegetables while they are in their raw or natural state, including herbs and tree nuts, but exempt certain categories that create less risk. They do not apply to 1) produce rarely consumed raw, such as artichokes, asparagus, or potatoes; 2) produce for personal or on-farm consumption; 3) produce that is not a Raw Agricultural Commodity; and 4) produce intended for commercial processing with

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a "kill step" that will adequately reduce microorganisms of public health concern. Unlike preventive controls, the new produce safety rules will require minimal recordkeeping. Growers would be required to document that certain of the standards are being met, but the rule would not require duplication of records already kept for other purposes.

The proposed rules provide that farms may establish alternatives to certain requirements related to water and biological soil amendments if the alternative is scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing food safety risks. In addition, states or foreign countries may request a variance from some or all of the rules if required by local growing conditions, provided the same level of public health is assured.

Certain farms would be subject to modified requirements. For example, farms and farm "mixed-type facilities" with average annual sales under $25,000 would not be covered under the new rules. These farms, however, will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug and Cosmetic Act. Farm mixed-type facilities (farms that are also engaged in activities outside the definition of "farm" that require food facility registration), may be subject to both the proposed produce safety rules and the preventive controls rules, such as an establishment that both grows and processes fresh-cut produce.

Similar to the proposed preventive controls, FDA proposes staggered compliance dates depending on the size of the farm. "Very small farms" would have four years from the effective date to comply, "small farms" would have three years to comply, and other covered farms would have two years to comply. In all cases, the time period for compliance would be extended for some water requirements.

Timeline for Implementation and Compliance

The effective date for both proposed rules is 60 days after the final rules are published in the Federal Registry. FDA continues to seek comments on the proposed rules through May 16, 2013. According to FDA, it will be at least a year before the final rules are published. Until then, food growers, manufacturers and distributors will have time to develop plans, policies, and procedures to conform to the new rules. FDA recognizes that partnership with the food industry is essential to the success of the proposed rules and will continue to provide technical assistance and outreach through public meetings, presentations, listening sessions, and guidance documents. ■

Brew is a partner at Faegre Baker Daniels in Minneapolis and leads the firm's nationally ranked Food Litigation and Regulation practice. She represents companies involved in all aspects of food production and distribution. **Lawrence** is an associate at Faegre Baker Daniels, practicing in food and agriculture litigation and regulation. She previously worked for an international producer and marketer of food, agricultural, financial, and industrial products and services.

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Small Businesses Tip the Scales for FSMA Exemptions

While smaller farms and facilities applaud FDA's proposed regulations, many experts in the food industry question whether these exemptions weaken FSMA's effectiveness at preventing foodborne disease | BY **TED AGRES**

About three-quarters of the U.S. farms that grow, harvest, pack or hold produce, as well as food companies that manufacture, process, pack, or hold food, are likely to be exempt from all or most of the requirements of Food Safety and Modernization Act (FSMA). This is because these farms and facilities will be considered to be "small" or "very small" businesses based on the value of their annual sales, end customers, or both.

On Jan. 4, 2013, the FDA published draft regulations on produce safety ("Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption") and for preventive controls ("Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food"). The two proposed rules, which total more than 1,200 pages, are the first of at least four regulations to implement FSMA. Rules on preventive standards for animal food facilities and on foreign supplier verification requirements are expected sometime this year.

But thus far, it appears that most U.S. farms and food companies will dodge many FSMA requirements. Despite this, the FDA estimates that about 90 percent of the produce grown and consumed in the U.S. will either be covered by FSMA, be consumed cooked, or be processed in plants capable of handling biological hazards associated with produce. However, while family-owned farms, small growers, and small business alliances laud the exemptions, many other food safety experts do not.

"Being a public health agency, FDA knows full well that small places can cause big problems," says David Acheson, director of the food and import safety practice at Leavitt Partners and former FDA associate commissioner of foods. "I don't honestly believe that FDA is very comfortable with this, but they have to do what they've been told and so will default to using Small Business Administration-type definitions, such as fewer than 500 employees or certain dollar amounts so there will be some consistency across the federal government as to how 'small' and 'very small' businesses are defined," Acheson tells *Food Quality* magazine.

Tester Amendment

As happens with nearly all major pieces of legislation, a variety of interest groups and lobbyists sought to influence FSMA as it was being crafted in Congress. For example, supporters of sustainable agriculture and family-owned farms urged Congress to exempt small growers and small processors, while many large corporations and trade groups urged inclusion regardless of size. In this case, the small farms won. The Tester-Hagan Amendment exempts small farms from having to comply with most FSMA requirements. Named after its cosponsors, Democratic Senators Jon Tester of Montana and Kay Hagan of North Carolina, the amendment is based on two premises: That FSMA's requirements would be too burdensome and expensive for small-scale growers and producers, and that food products from small farms and businesses aren't as risky as those produced by large operators.

"Let's face it: Dangerous foodborne outbreaks don't start with family agriculture," Tester said after introducing the amendment in 2010. "Food produced on that scale shouldn't be subject to the same expensive federal regulations as some big factory that mass produces food for the entire country."

The Tester Amendment exempts farms from most FSMA requirements if they have less than $500,000 in average annual sales and more than half the sales go to "qualified end-users," defined as consumers anywhere or to restaurants or retail food establishments in the same state as the farm or not more than 275 miles away. (These farms may need to comply with certain labeling requirements even if they are exempt.) FDA can withdraw the exemption if the farm is directly linked to a food-related outbreak or to mitigate or prevent an outbreak.

The draft produce rule also excludes any produce that is considered low risk with respect to biological hazards. Examples include produce that is rarely consumed raw, such as potatoes, or that will undergo processing that includes a kill step, such as green beans intended for canning. The proposed rule also does not apply to produce for personal or on-farm consumption.

The rule, which is open for public comment until May 16, 2013, exempts farms having less than $25,000 in average annual sales. According to the FDA, 40,496 domestic farms (including 285 sprout farms) will be fully subject to FSMA rules. Fully or partially exempt would be 75,716 farms that fall under the Tester Amendment provisions and 34,433 farms having less than $25,000 in sales. By this count, 73 percent of all U.S. produce farms

would be fully or partially exempt from FSMA requirements. However, FDA notes that, as a group, food businesses with less than $500,000 in annual sales produce less than 1 percent of all U.S. food by dollar value.

Small farms that do not come under the Tester Amendment would be given extra time to comply with FSMA requirements. Sixty days after a final produce safety rule is published in the *Federal Register*, non-exempt "small businesses" (those with less than $500,000 in annual sales) would have three years to comply with requirements. "Very small businesses" (those having less than $250,000 in annual sales) would have four years to comply, while other businesses would have two years. The smallest farms, those having less than $25,000 in sales, are exempt.

"We know one-size-fits-all rules won't work," said Michael R. Taylor, deputy FDA commissioner for foods and veterinary medicine, when the rules were published back in January. "We've worked to develop proposed regulations that can be both effective and practical across today's diverse food system," he said.

Others are not so sanguine.

"Income has no relationship to risk of bacterial contamination," says David W. Plunkett, senior staff attorney at the Center for Science in the Public Interest in Washington, D.C. "Therefore we see absolutely no reason to suppose that these [small] facilities and farms are inherently safer than larger facilities and farms. One likely result of the Tester Amendment is that food from Tester facilities and farms will begin to bear a disproportionate share of the illness burden," Plunkett tells *Food Quality* magazine. "We can't ignore the fact that Tester weakens FSMA's effectiveness at preventing foodborne disease."

Preventive Control Rule

A bit more complicated are small businesses exemptions in the proposed preventive control rule. In general, the rule would require facilities that manufacture, process, pack, or hold food to register with FDA. Unless exempted, these facilities must have a hazard analysis and preventive controls plan in place. (Farms are generally not required to comply unless they are a "mixed use" facility that also employs a processing activity, for example, chopping vegetables.)

The preventive control rule would establish modified requirements for "qualified facilities"—that is, facilities that either meet the Tester Amendment definition for business size and customer base, or that are "very small" businesses. For the latter, FDA is proposing three different categories and is requesting comment on each. The options are average annual revenues of $250,000, $500,000, or $1 million.

However defined, these very small facilities and the Tester Amendment-level firms would only be required to certify that they have identified potential hazards associated with the food being produced and are implementing and monitoring preventive controls measures. Alternatively, they could submit documentation that they comply with a state, local, county, or other non-federal food safety law, including relevant laws and regulations of foreign countries. In either case, they wouldn't have to submit any actual plans.

FDA estimates that about 97,646 domestic food manufacturers, warehouses, and wholesalers would fall under the preventive control rule. If the exemption were set at less than $250,000 in annual sales, FDA says 46,097 of these firms, or 47 percent, would be exempt from hazard analysis and risk-based preventive controls. If set at less than $500,000, 57,411 or about 59 percent would be exempt, and if less than $1 million, 74,985 or about 77 percent of the firms would be exempt.

Like the produce safety rule, FDA is accepting comments on the draft rule until May 16, 2013. Sixty days after publication of a final rule, large facilities will have one year to comply with requirements, while non-exempt small businesses would have two years and non-exempt very small businesses would have three years.

"I'm not sure it makes that much difference whether a firm has $250,000 or a million dollars in sales," says Acheson. "But part of the reason FDA is asking for comment is if they get an overwhelming response saying to make the definition as stringent as possible, it gives them cover to do so. If they don't get it, they will stick to where the comments lead them."

Both Acheson and Plunkett wish that small businesses had been treated differently.

"If I were calling the shots and had the resources, I would be putting preventive controls requirements on all small businesses irrespective of size if they ship through interstate commerce," Acheson says. "But I would also build robust programs to educate and train the small producers. The challenge is that many of them are not sophisticated enough to understand what they need to do."

Plunkett believes that all food processors should conduct science-based assessments of risk and implement preventive measures. "The rule should be structured to accommodate size without overlooking mitigation or elimination of risk," Plunkett says. "There is a logical lapse in Tester's assumption that a processor who can't afford to implement reasonable preventive measures is somehow going to always produce safe food." ■

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Hygiene Monitoring Strategies that Hit the Mark

Rapid methods for soil detection, indicator microbial loads, and pathogen detection in hygiene monitoring programs have accelerated due to new technologies spurred on by increased verification enforcement from federal regulations and GFSI agendas | BY **CHARLES GIAMBRONE, MS**

The emphasis on validation had begun in 2002 with the advent of the Microbial Sampling of Ready-To-Eat Products for the FSIS Verification Testing program, the subsequent revisions in June 2003 with 9 CFR Part 430. Then on March 15, 2006 with the alternative control measures coupled with the EIAOs and a new type of risk based sampling programs for Lm for food contact and environmental surfaces.

Also, due to the requirements by the newly established Food Safety Modernization Act (FSMA) enacted into law by Congress in early 2012, a number of market sectors have already have mandated enforcement including validations using hygiene monitoring technologies.

The rise in implementation of the Global Food Safety Initiative (GFSI) programs, especially in the latest GFSI-approved versions of SQF, BRC, and now FSSC 22000 here in North America, has made validation mandatory via the various hygiene monitoring modalities.

Particularly, the new SQF edition 7 has an increased emphasis on Validation-Verification of hygiene monitoring/sanitation in module 11 and in module 12 as well as "mandatory elements." This includes documented and frequency for validation of chemical concentrations and procedures (SSOPs) as well as the food contact and environmental surface hygiene monitoring validation methods and procedures.

Similarly, with the new BRC Issue 6, there is this enhanced enforcement on Validation-Verification in Clause 4.11.4 in Housekeeping & Hygiene. The Housekeeping & Hygiene clause is also considered a Fundamental Clause. Also, 4.9.1 emphasizes Chemical & Physical Contamination Control.

Zone Sampling Considerations

In both food processing plants as well as food service operations, many food safety experts and knowledgeable sanitarians view pre-requisite program controls as a multi-barrier system akin to a dartboard. We all know the Zone 1 or "bull's eye" is the actual food contact zone. Obviously, all hygiene control programs must prevent pathogens and spoilage microbes from compromising this critical zone.

However, the sound proactive approach is to establish and maintain microbial control outward from Zone 2, which are the indirect food contact areas, to Zone 3, the immediate environmental zones around the food processing area, finally to the Zone 4 area that is the gen-

eral environmental environs of the food plant. The objective of any sound hygiene monitoring program is to not merely focus on the bull's eye, but be as assiduous in your program as you can to control Zones 4 and 3, thereby minimizing the risk upon Zones 2 and 1.

Therefore your hygiene monitoring validation programs must include both the Food Contact (Zones 1 and 2) and Environmental (Zones 3 and 4) for soil removal, as well as indicator and pathogen microbe validations. The frequencies will of course vary based upon the risk assessment of the plant's HACCP program for each and every product manufactured at a specific plant site.

For example, on a post kill/cooked-RTE processing piece of direct food contact equipment, the frequency that equipment unit will be assayed on a weekly basis will be far greater than a raw meat blender or mixer under the hygiene sampling plan for that facility.

The selection of sites either during a pre-operational sampling or during a scheduled shift cleanup or even operational assessments must be selected based upon a program's risk assessment of each site, but must be selected by the sampling team in a manner not to tip off the sanitation staff. The sampling matrix in its entirety must cover all critical food contact and environmental sites within the program's mandated frequency. This is vital in order to generate a validation history that accurately reflects the realities of the facility's design and operation.

Methodologies

There are a myriad of systems and devices to assess hygiene levels on both food contact and environmental surfaces. Some employ sophisticated microbial detection methods utilizing polymerase chain reaction (PCR) with sophisticated instrumentation. However, I will focus on some of these companies that have both soil detection, indicator microbial detection, and pathogen detection systems that are designed for hygiene monitoring programs in concert with plant sanitation.

There are three primary tools to sample a surface: the classic swab, the sponge, and the wipe. Many studies have been done through the years to ascertain which extracts the most soil or microbes for sampling. But the critical factor is that one must understand the limits of the sampling system.

For example, a swab is an excellent tool to assay a gasket or a tight area, but has a lower recovery of viable microbes than a sponge or wipe. Meanwhile a sponge swab or RODAC plate is effective for a flat surface, while a curved tank wall may prohibit the use of RODACs but is conducive to sampling by a sponge system.

> QAC sanitizers have been known in some instances to create false positive readings with ATP, while oxidizing sanitizers can create false negatives when a freshly sanitized surface is sampled for ATP.

A comprehensive national study published in *Applied and Environmental Microbiology* utilized both sponge sticks (3M), and wipes to recover *Bacillus anthracis* spores showed that the gauze wipes had 35 percent rate of spore recovery while the sponge sticks had a recovery range of 26 percent to 36 percent.

Using both methods, the sponge, as is typically done, is placed into a sterile sampling bag or stomacher bag and is transported with either a peptone water or other recovery broth. A recovery or resuscitation broth is critical for stressed/sublethally injured vegetative microbes, but is not essential for spores.

The utilization of the sponge stick or solar-cult devices enables one to use one sponge face for horizontal direction of a surface, the other for vertical, and the edges for the diagonal of the same sampling surface. This is done omitting the variable of handling the sponge directly with gloved hands.

Best recovery of low numbers for enumeration is achieved via membrane filtration and plating. For pathogen presence/absence sequential incubations in AOAC BAM approved broths is done coupled with confirmation by selective platings. Sponge systems are also utilized for carcass detection of EHEC microbes in numerous USDA plants.

Soil detection systems. There are many different ATP units with varying features. All have evolved into more compact units, with self-containing ATP swab pens coupled with excellent software to download and interpret data for your hygiene validation verification programs.

There are many units on the market, but there has been consolidation of some companies the past 10 years. Examples of hygiene monitoring with ATP units include: AccuClean (Neogen), Charm, CleanTrace (3M), Ensure (Hygiena), HyLite (EM Millipore), and SystemSure Plus (Hygiena). Most utilize a swab that is pre-moistened. The AccuClean has a small sponge-like sampling area instead of a swab. Some utilize a lyophilized pellet of the enzymes that gets reconstituted; others, like Hygiena's Ensure and SystemSure Plus use a liquid system.

Once the surface is assayed, the ATP swab pens are activated by twisting, cracking the chamber containing the enzymes needed to activate the firefly reaction, then placed into the ATP luminometer chamber where the photodiode measures the Relative Light Units (RLUs) released. The higher the RLU reading, the greater the soil. Unfortunately, RLU scales vary widely between ATP luminometer. This historically was done by manufacturers to tie the user into one unit since all the surface ATP swab history is based upon a luminometer type's specific scale.

Years ago, faulty attempts were made to correlate ATP with microbial levels. This is highly problematic because ATP assays measure organic soil load that is lowest in bacteria. Yeasts and molds have much higher levels of ATP per microbe than do bacteria, so if a soil matrix has active spoilage fungi, the RLU reading will be higher than with vegetative bacteria.

Establishing a baseline for pass/fail for your food contact and environmental sites is critical. All these ATP luminometers enable you to set multiple pass/fail RLU readings for specific sites, plant areas, or equipment depending again upon the nature, surfaces, and dynamics of the processing operation with that equipment

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or environmental site. Baseline studies need to be done very carefully when an ATP hygiene monitoring program is set up in a specific facility so the pass/fail limits are meaningful, reliable, and reproducible.

There are specifically designed ATP pens to sample water and clean-in-place (CIP) rinsate systems. Hygiena's AquaSnap is one example to sample the final rinse of a CIP cycle (prior to sanitization) and assess the level of ATP soil in the final rinse. This is a useful tool for hygiene monitoring of CIP system cleaning validations.

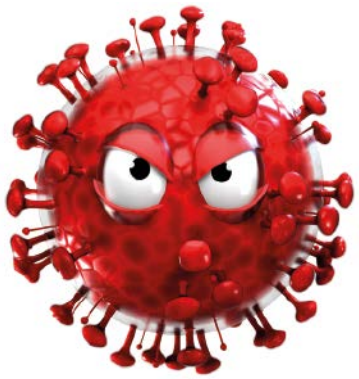
The other cautionary note both for ATP systems and for any other soil enzyme detection system is the point in the sanitation process it is best utilized. Many sanitizers can and will interfere with the enzyme reactions. Quaternary ammonium compound (QAC) sanitizers have been known in some instances to create false positive readings with ATP, while oxidizing sanitizers can create false negatives when a freshly sanitized surface is sampled for ATP.

I recommend that since ATP is a barometer of soil level, it's best utilized after the cleaners have been completely rinsed but before the sanitizer is applied. That way if there is a fail reading, the surface can be re-cleaned prior to sanitization. This omits the chance of reactions between ATP pen enzymes and the sanitizer. It is also applicable for protein detection enzyme systems. Some will give a dramatic false positive when a clean surface sanitized with peracetic acid is sampled.

Speaking of non-ATP soil detection systems, these are qualitative, colorimetric swab pens that can detect, using a color scale, the presence of protein residues. Neogen has its AccuClean for protein while Hygiena has its ProClean unit. While these do not provide a quantitative validation of the hygiene monitoring, they are user-friendly tools that permit sanitation supervisors or managers to ascertain if a critical piece of equipment must be re-cleaned. However, these protein swabs are not to be used for allergen validation since they measure general protein, and do not target the specific allergen you are seeking to remove via the SSOP for that equipment or area. Rather specific allergen detection systems like Neogen's Reveal Rapid 3D kits using lateral flow technology are required for allergen hygiene monitoring.

Hygiena also has an enzyme detection swab for lactose or sucrose soil residue: SpotCheck Plus, which turns green in the presence of either sugar residue. This is useful for dairy plants, confectionary candy, and beverage plants.

Indicator Microbe Testing. The typical methodology for sampling either food contact or environmental surfaces for indicator microbes involves a standard swab, in some cases with a neutralizing



buffer or a Letheen neutralizing broth that is needed to neutralize any residual sanitizer. In a hygiene monitoring program, one should be sampling for either indicator or pathogenic microbes, after the sanitizer(s) have been applied.

Indicator microbes will depend upon the nature of the operation. In addition to Total/Aerobic Plate Count, indicator microbial tests include *coliform-E.coli*, *Enterobacteriaceae*, yeast and mold, and *Staphyloccus spp.* For example, meat, poultry, or dairy plants will test either for *coliform-EC* or *Enterobacteriaceae*, while bakery operations will typically assay for yeast and mold.

Contact slides have been around for some time but some user-friendly versions include the Envirocheck line from EM Millipore or the Hylab dip slide paddles marketed by Neogen. In addition, as discussed, RODAC plates can be manufactured with a variety of agar media for the targeted indicators.

Hygiena, using its multipurpose hygiene reader Ensure, has the capability with its Microsnap swab system of providing a facility with a result for *E.coli* or *Enterobacteriacea* in less than seven hours. It relies on a "bioluminogenic" reaction involving specific enzymes generated by the specific indicator group to measure and detect the indicator

Like ATP, pass/fail levels for indicator microbes depend upon the food contact or environmental site being sampled. However, a guideline I prefer is one advocated in the British Columbia Centre for Disease Control's document on environmental hygiene monitoring that has an interpretation of a "clean" surface being <45 cfu (colony forming units) , "contaminated" surface being 140-260 cfu, with "very contaminated" being > 260. This document is an excellent primer on how to approach hygienic monitoring, critical environmental sites to assay in generic environmental terms, and sampling using both swab and sponge assay methods.

Air monitoring is also a vital component of your hygiene monitoring program. While many plants utilize the classic air sedimentation method employing petri dishes left exposed to a specific area for 15 minutes, this method relies on the serendipitous deposition of microbial particles landing onto an agar surface.

Air sampling units that either utilize an agar plate, or an agar strip that actively pulls a defined volume of air within the area/room to be sampled are preferred. Particularly air sampling units like the RCS units (Reuters Centrifugal Samplers) like the type manufactured by EM Biotest enable you to actively sample and count an airborne microbial density for total count, coliform, or yeast and mold. They provide a cfu count/cubic meter or cubic foot of sampled air. Seasonal air sampling enables a plant's program to validate sanitation of air handling units, intake vents, and cooling tunnels/spiral units. Therefore, air sampling has become a critical component of a facility's hygiene monitoring program.

Pathogenic Detection Systems. The sponge swab methods mentioned previously for indicator microbes are also typically used for environmental and food contact hygiene monitoring for *Salmonella* and environmental *Listerial* species.

Neogen, using the same lateral flow technology utilized for allergen validation, has a series of Reveal systems to

detect *Listerial spp.*, *Salmonella*, and *E. coli* 0157:H7. These are rapid detection systems and provide the end user with a result after 15 minutes for environmental *Salmonella*, 20 minutes for environmental *Listeria*, and eight hours for *E.coli* 0157:H7. Because of its lateral flow design, the Reveal systems are strictly presence or absence, but are very rapid in their result for presumptive positives.

Hygiena has a presence-absence test that employs a self-contained swab medium with a large swab head, InSite. The InSite swab gets incubated at 37 degrees Celsius for 30 to 48 hours and provides a color scale to qualitatively assess the severity of environmental *Listerial* species for presumptively positive *Listeria*. The quicker the growth medium turns a brownish color, the higher the level of environmental *Listeria* sampled. This method is cost effective and is user friendly, and can successively grow stressed/injured *Listerial* species even amongst a high microflora.

3M has a modification of their Petrifilm line (3M Petrifilm Environmental *Listeria* plates) that quantifies the level of environmental *Listerial* species and is AOAC approved. This is significant because in many instances for environmental or even food contact surfaces, a presence or absence test does not provide sufficient information. By quantifying, you can correlate the severity of the contamination levels with the zone sampled in the plant. The results are achieved in a 27 to 31 hour time frame, so corrective actions can be implemented into the plant hygiene program.

Now What?

All the methods discussed have accuracy, reproducibility, and a sense of timeliness. How we interpret the data and track the trends in a hygiene monitoring program will either improve a program, let it remain stagnant, or, at worse, cause a major food safety crisis in a plant. We can use the hygiene monitoring program for both food contact and environmental zones in a reactive or a proactive manner. The software programs to organize and track the data for many of these systems or devices are already available.

If we are truly promoting the continual improvement of a facility's food safety program, the data must be utilized in a proactive manner to teach staff on every level how to continually improve the facility's hygiene programs. To be sure, the GFSI programs and the regulatory bodies now do demand that your data serve as roadmap for continual improvement of your PRPs and HACCP programs. ■

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REFERENCES FURNISHED UPON REQUEST

Don't Let Third-Party Audits 'School' You

The five factors to consider for pest management documentation in order to be audit-ready at any time

BY **ZIA SIDDIQI, PHD, BCE**

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

Imagine you're a student who is aware of a major exam scheduled for the end of the month. Instead of studying throughout the week leading up to the exam, you decide to cram the studying into the final 24 hours prior to the exam. You might be thinking to yourself, "That leaves far too much to chance—what if there isn't enough time to cover a certain concept in-depth, or to ensure a full understanding of the subject on the whole?"

Those are the same concerns that come along with preparing for a third-party food safety audit. If a facility manager leaves preparation for the last few weeks leading up to the audit, it will most certainly spell t-r-o-u-b-l-e for his or her food safety audit score. Because business success hinges on an outstanding audit score, it's easy to understand the dangerous consequences a lack of audit-readiness can bring.

Three of the most common third-party audit standards for food processing facilities are Safe Quality Food (SQF), the British Retail Consortium (BRC), and American Institute of Baking (AIB). Third-party auditors such as NSF and others use those standards to ensure facilities are compliant with the criteria of the Global Food Safety Initiative (GFSI), which was created in 2000 by a group of international food retailers to help ward off food safety hazards. Although GFSI does not conduct audits, major retailers like Wal-Mart require all suppliers to meet GFSI standards. That means your facility needs to meet or exceed audit standards every time.

Pest management can account for up to 20 percent of the total audit score, so ensure you are proactively preventing pest activity by implementing an ongoing, comprehensive Integrated Pest Management (IPM) program. With a focus on strategies like sanitation and facility maintenance, IPM helps keep facilities pest-free, which is exactly what auditors like to see. However, without proper documentation that spans a length of time, it will be virtually impossible to prove the success of your pest program.

Although the varying audit standards and criteria can be confusing at times, don't let them "school" you. Keep in mind the following top five audit problems when it comes to pest management documentation in order to be audit-ready at any time and achieve high scores.

1. Lack of training or certification proof for pest management professionals. Although your pest management professional may have the proper training or certification required to perform the job, it won't mean anything to auditors if that evidence is not housed at your facility. Auditors may require any or all of the following documents as part of their audit:

- A photocopy of the registration or certification document for every individual who regularly executes pest management services on the property, if required locally
- Confirmation of Good Manufacturing Practices (GMPs) training for all individuals who are held accountable for performing pest management processes
- Written evidence that the IPM provider was trained in the proper and safe use of pest management materials

2. Written proof of changes to service and materials, following signing of the contract. Successful IPM programs are dynamic rather than static and change over time based on a number of factors, so it's important that you remember to document all changes to the program after you sign the contract with your pest management professional. Written proof of even the slightest changes to the elements of your current pest management services, and reasons for the changes, is required. Also consider including a list of roles and responsibilities that explains the duties of your facility's staff against those of the pest management provider's team.

Consider speaking with your pest management professional about how you can work together to achieve high audit scores.

3. Corrective actions are not based on pest sighting and pest activity reports. Ensure that your pest trend analysis and recommendations for sanitation and building maintenance issues provide the basis for all corrective actions that help manage insect activity at your facility. Third-party auditors often deduct points from audit scores when facilities do not have written documentation of pest sightings and pest activity, accompanied by an explanation of the resulting counteractive efforts.

4. No records of insects found in light traps and pheromone traps or corrective actions, although the traps are inspected regularly. Documentation of all services provided to light and pheromone traps are typically required by auditors. This includes the types of insects, as well as the quantities, that are found when the traps are checked. Although you may include this in your documentation, that doesn't paint a comprehensive picture for auditors—they will also need to have an understanding of the corrective actions you took to manage the pest problem. It's important that you can show written documentation of all steps:

a) services performed to the light and pheromone traps,
b) the results of each trap check, and
c) the corresponding actions taken to help mitigate pest activity.

5. Missing record of actions that were implemented following the annual pest control assessment. Almost all auditors require that pest management providers hold an annual facility assessment, which helps determine areas of improvement or necessary changes for IPM programs. Again, you should ensure that all of the corrective actions implemented after the annual assessment are documented, along with proof that those actions were actually executed. Without showing that the counteractive efforts were executed and completed, you may lose points on the pest management portion of your audit.

Now that you've armed yourself with this information on the top five common pitfalls when it comes to documentation, consider speaking with your pest management professional about how you can work together to achieve high audit scores. By working hand in hand to cover your bases, you'll be on your way to acing your next big exam—your food safety audit. ■

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IPM and the New FSMA

A new rule under the Food Safety Modernization Act (FSMA) will require facilities to develop and execute written food safety plans that detail potential hazards, corrective actions, and more.

Many facilities will already meet the rule's stipulations because they follow the standards of major third-party auditors such as AIB, NSF, Silliker, and GFSI compliant standards like SQF, BRC, etc. However, smaller food processing plants without formal food safety plans will likely be heavily impacted by the new FSMA regulation. Regardless, an Integrated Pest Management (IPM) program can help facilities—large and small—ensure they meet or exceed FDA standards. The following chart demonstrates IPM's role in the food safety plan mandated by the new FSMA rule, calling attention to key elements of focus.

FSMA Rule Requirements	Elements of an IPM Program
Hazard analysis to identify and evaluate reasonably foreseeable hazards	**Comprehensive inspection** to identify pest hot spots and risks
Preventive controls to minimize hazards	**Emphasis on pest prevention** through sanitation, facility maintenance, and non-chemical methods
Monitoring procedures to ensure preventive controls are performed consistently	**Ongoing monitoring** to pinpoint pest activity and conducive conditions
Corrective actions to manage problems and prevent reoccurrence	**Corrective actions** to help manage pest activity
Verification activities to measure effectiveness of preventive controls, including periodic reassessment	**Regular service visits**, combined with an **annual facility assessment** and **pest trend analysis**, to determine effectiveness and areas of improvement
Recordkeeping to keep track of the plan and all resulting actions	**Comprehensive documentation** to record pest issues and corrective action

‘Boat-to-Plate’ Traceability

With a global quality hub, the seafood industry can verify product quality on the boat, at the fishery, with the at-sea and land processors, and at the distributor | BY **STEVE WISE**

A global quality hub means knowing whether or not seafood meets specific requirements as soon as it is produced.

Listeria in wild Alaskan sockeye salmon and apples. *Salmonella* in peanut butter and cantaloupe. *E.coli* in spinach and lettuce. These are only a few of the recent reasons that the FDA continues to implement stricter and more specific food safety standards for both domestic and imported foods. The latest advancement is the announcement of two long-awaited food safety rules that will force entire supply chains to evaluate processes and procedures. Facilities that manufacture, process, pack, or hold human food must look for ways and means to implement the changes before compliance deadlines.

Something's Fishy

In the next phase of the Food Safety Modernization Act (FSMA), the FDA plans to address the fact that approximately 15 percent of the food consumed in the U.S. is imported by proposing rules that would target importers. By implementing a means to verify that food products grown or processed overseas are as safe as domestically produced food and determining accreditation standards to improve third-party food safety audits overseas, the FDA will move another step closer to its goal of ensuring that the U.S. food supply is safe.

The FDA is not the only voice to be heard. In October, restaurant owners, culinary leaders, and more than 500 of the nation's top chefs—Barton Seaver, Mario Batali, Rick Bayless, Daniel Boulud, Thomas Keller, Jacques Pepin, Eric Ripert, and Michael Symon, among them—joined Oceana, the largest advocacy group working solely to protect the world's oceans, in a letter to the U.S. government calling for traceability for seafood from boat to plate "in order to prevent seafood fraud and keep illegal fish out of the U.S. market."

Ninety-one percent of the seafood consumed in the U.S. is imported, but less than 2 percent is inspected. This, and the fact that many fish when filleted look quite similar, makes it simple for an anticipated shipment of white tuna to actually be escolar, which can lead to severe intestinal issues due to the laxative effect of the wax esters in its flesh. Recent studies show that seafood mislabeling can happen as often as 70 percent of the time for these types of fish—at any point of the supply chain including the restaurant, the distributor, or the processing and packaging plants.

Beyond cheating the customers, seafood fraud can have costly—even deadly—consequences. For example, it can threaten human health with unexpected contaminants, toxins or allergens; create a market for illegal fish taking business from honest fishermen; make it nearly impossible to sustain conservation efforts when consumers cannot make eco-friendly, informed decisions; and mislead the general public to believe the marine environment is healthy, when in reality overfishing is abundant and many species are in serious trouble.

This does not have to be the state of the seafood industry. In reality, the chefs' demands can easily be met by going beyond the basic regulations and implementing available technologies.

Global Quality Hub

A major shift can be seen across the food market as manufacturers are utilizing cloud computing and manufacturing intelligence to improve product quality, ensure current and future compliance, and minimize IT expenditure and support costs. Cloud computing enables facilities at all points of the food supply chain to collect, input, and analyze data through a global quality hub. Therefore, a grocer can ensure that there are no metal fragments in the frozen pizza it sells, a creamery feels confident that the milk it receives to make ice cream has been properly flash pasteurized, and chefs know they will be serving the same fish to their patrons that they ordered from their suppliers.

Powered by a statistical process control (SPC) engine, a global quality hub can create the "boat-to-plate" traceability for the seafood industry. With multi-lingual, mobile devices such as tablets and smartphones, data can be easily collected from anywhere around the world, from nearly any system, and made immediately available to the manufacturer. This means knowing whether or not a product meets specific requirements as soon as it is produced. There would not be a need to wait for shipments to arrive at the receiving dock when Certificates of Analysis (COAs) could be created in real-time—at the time the product is being produced by the supplier.

There would not be a need to wait for shipments to arrive at the receiving dock when COAs could be created in real-time.

For example, nearly 70 percent of imported tilapia comes from China, which is the third largest fish and shellfish importer to the U.S. Unlike the open-water systems of the U.S., China's pond and cage cultures are two common ways of farming tilapia. However, these closed systems limit the ease of expelling fish waste, uneaten food, and chemicals used to treat disease, increasing the risk of creating a polluted environment. By implementing quality checks by the fisherman, it is possible to ensure that the fish being sent to the U.S. were in fact healthy when they were caught. After the first check, the tilapia may make several stops before reaching U.S. soil, making it quite simple for the less-than-reputable to make a swap with escolar along the way.

With a global quality hub implemented by seafood manufacturers, tilapia

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can be checked on the boat, at the fishery, with the at-sea and land processors, as well as at the distributor through easy data entry via mobile computers and smartphones. The seafood producers can then send the resulting, real-time dashboards, analysis reports or email notifications displaying lot numbers, temperatures, check-in times, visual indicators, and general condition of shipping materials and delivery vehicles to the grocers and chefs to confirm the type of fish they will receive, and ultimately ensure the highest quality of product for the customer. Supermarkets can take it one step further and enter point-of-sale data such as on-site inspection, shelf placement, and in-store location into the same global quality hub to inform the producer that the product is also being displayed and sold properly.

Beyond the Fishing Hole

Ensuring traceability around the world and throughout the food supply chain is just one of the benefits of a global quality hub. Because all the data is stored in a single repository, food manufacturers improve their readiness for audits because they can run a report of data already in the system to prove they are in compliance with required quality checks.

Furthermore, upon entering the second life of the data, there are numerous opportunities for process improvement due to variation or overfill. With minor adjustments, both waste and costs can be driven down resulting in hundreds of thousands, if not millions, in cost savings. With tools available that incorporate real-time automation within a global quality hub, food manufacturers can meet time-specific regulatory requirements by scheduling quality checks at precise intervals and incorporating visual, audible, or electronic reminders. With the centralized data repository and specification limit automation capabilities of a global quality hub, these manufacturers can easily comply with SSOP (sanitation standard operating procedures), FSMA, 21 CFR Part 117, Hazard Analysis and Critical Control Points (HACCP), and other regulatory requirements.

As more regulations are passed, food manufacturers face the growing concern of ensuring compliance based on many different stipulations. The key to compliance with both traditional and the new regulatory framework is embracing advancements in technology, such as cloud computing, mobile devices, and global quality hubs. With an effective system in place, food manufacturers can utilize manufacturing intelligence to mitigate the risk associated with product contamination and recalls, and optimize manufacturing operations to deliver a low-cost, high-quality product to the customer. ■

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REFERENCES FURNISHED UPON REQUEST

Raw Materials

INGREDIENTS/ADDITIVES

When Safe May Not Be Safe Anymore

Re-evaluating food additives on the GRAS list in light of current science and advanced testing technologies | BY **MAYBELLE COWAN-LINCOLN**

Those of us who remember riding bicycles without helmets and standing up in the backseats of our parents' station wagons know that what we once thought of as safe may have been anything but. Armed with new information, we changed our behaviors. But what about food additives that have been considered safe for decades? Are there substances considered innocuous in the 1950s that should get re-evaluated for safety in light of current toxicology knowledge and modern testing technologies? Are there additives once considered safe that should now be banned? That is the question many people are asking about the emulsifier brominated vegetable oil (BVO).

BVO is a synthetic chemical used as an emulsifier in citrus flavored drinks in the U.S. including Mountain Dew and Gatorade from PepsiCo, Powerade, Fanta Orange and Fresca made by Coca-Cola and Squirt and Sunkist Peach soda from the Dr. Pepper Snapple Group. Derived from corn or soybeans, BVO contains bromide atoms that weigh down the citrus flavor and allow it to mix with the sugar water base of the drink. Without BVO or another emulsifier, the fruit flavor would separate and rise to the top. Approximately 10 percent of drinks sold in the U.S. contain BVO.

The use of BVO as an additive dates to the 1930s. When Congress passed the 1958 Food Additives Amendment to the federal Food, Drug and Cosmetic Act, it was placed on the generally recognized as safe (GRAS) list. There are two ways an ingredient can be included on the GRAS list:

- For substances like BVO, in use prior to 1958, a GRAS determination can indeed be made based on common use in food consumed by a significant number of people over a substantial amount of time
- Newer substances can be judged GRAS based on a "consensus of qualified experts" who have reviewed scientific data and currently available information

Although BVO was among the substances grandfathered onto the GRAS list, in the late 1960s and early 1970s, the Flavor and Extract Manufacturers' Association (FEMA) expert panel decided to evaluate many of these older additives. At that time, they decided that there was insufficient data to support a GRAS claim. The FDA generally follows their recommendations, and in 1970 they revoked the GRAS status of BVO and requested that FEMA study the compound in mice, rats, dogs, and pigs. After several submissions of safety data, the FDA made an interim ruling, pending more studies, that BVO was safe in fruit-flavored beverages in amounts of up to 15 parts per million. But now, over 35 years later, no further studies on BVO have been conducted, and the interim status remains unchanged.

For many experts, this is simply unacceptable. Michael Jacobson, PhD, co-founder and executive director of the Center for Science in the Public Interest,

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believes that the FDA takes too lax an attitude toward the dangers potentially posed by additives. "The FDA has not been nearly cautious enough in protecting the public from food additives and GRAS substances that cause, or may cause, health problems at the levels consumed," states Dr. Jacobson.

But the FDA is confident that they have acted with proper vigilance. When questioned about the necessity of conducting further studies on BVO to remove its interim status—either by declaring it GRAS or banning if from the U.S. food supply as it has been in the European Union and Japan—Patricia El-Hinnawy, FDA press officer, was dismissive. In an email, El-Hinnawy states, "The FDA understands that some consumers may have concerns about brominated vegetable oil (BVO) in food products. Based on its review of the science, the FDA has determined that BVO is safe and presents no health risks at the permitted level of 15 parts per million."

However, BVO exposure is not limited to diet. Bromine atoms slow down chemical reactions that cause a fire thereby slowing down the spread of flames. Consequently, they are used in flame retardants that are added to polystyrene foam cushions, children's products, and plastics used in electronics. Research in animals and humans has shown that bromide is building up in tissue and breast milk, and it has been linked to impaired neurological development, reduced fertility, and early puberty.

What Makes a Substance Safe?

So how does the FDA define safe in a food ingredient? There are two calculations the agency uses to evaluate the potential toxicity of an additive. The first is the Acceptable Daily Intake (ADI), derived from a review of the substance's clinical nature and available toxicology studies, plus relevant safety factors. It is an estimate of the maximum amount of a substance that a person can consume daily over their lifetime without significant risk of harm. The other consideration is Estimated Daily Intake (EDI), the predicted dietary exposure based on how often a person consumes the ingredient in any food on a typical day, the size of the portion, and how much of ingredient is found in the foods.

Simply put, if the EDI is less than the ADI, the ingredient can indeed be considered safe.

This safety equation is simple, but gathering accurate dietary exposure information to assess EDI is not. For the daunting task of determining exactly what and just how much Americans eat, the FDA relies primarily on the National Health and Nutrition Examination Survey (NHANES), conducted by the Centers for Disease Control and Prevention (CDC). This survey asks thousands of participants to recall everything they ate over a two-day period. From these answers, an overall view of American eating habits can be extrapolated.

Some experts, however, feel that two days provides an insufficient sample of eating habits, and asking consumers to recall everything they ate for a period of time in the past leaves a large margin of error. So the FDA also relies on surveys conducted by private firms. These studies last 14 days and often use daily food diaries kept by participants. To further inform their EDI estimates, the agency uses data reporting how much of certain commodities enter the marketplace annually, tests to monitor chemicals and pesticides as well as nutrient elements in foods and biomonitoring data from blood and urine specimens from randomly selected NHANES participants.

How do New Ingredients Make GRAS List?

But since 1997, the FDA's GRAS determinations have not involved testing by the agency's staff. Rather, the fact gathering and proof have been left up to the private sector, usually to companies looking to market a new product with a new additive. The GRAS Notification Program is a voluntary process by which an individual can inform the FDA that a substance used in a particular product is GRAS. A notification, sent to the FDA's Office of Food Additives, includes:

- A brief description of the substance
- The intended use of the substance
- The basis for the GRAS determination

The notification should include information about the chemical and toxi-

cological properties of the substance and any data that would not support a GRAS determination. Finally, the notifier must explain why, in light of the totality of the information, they have concluded that the substance should be GRAS.

When is a Second Look in Order?

In November 2011, The Pew Charitable Trusts, the Institute of Food Technology (IFT), and the journal *Nature* cosponsored the workshop Perspectives on FDA's Exposure Assessment to Ensure Substances Added to Human Food Are Safe. The event brought together more than 70 experts from academia, industry, government, and public interest groups who agreed that the FDA's current system for monitoring food safety has room for improvement.

One suggestion that came out of the workshop was periodic reassessment of consumers' exposure to GRAS substances. Circumstances under which participants would recommend a toxicity re-evaluation include:

- Significant dietary changes
- FDA receives a petition for a new use of an approved food ingredient or additive
- New toxicological information becomes available
- Changes are made in manufacturing and sourcing of the ingredient that could affect its identity
- Improved measuring tools are available
- Congress or an international regulatory body questions the safety of a substance

In the case of BVO, dietary exposure in at least one population has increased dramatically. "Gamers," or teens who play video games hour after hour, use sodas to give themselves the energy boost they need to stay awake and focused. And according to the Pew Research Center, nearly every U.S. adolescent plays video games. Serious gamers who play for six, 10, or 12 hours often drink a 20-ounce soda every hour. When you do the math you discover that a 20-ounce soda every hour over eight hours adds up to more than 4.7 liters. This booming market has not gone unnoticed by soda manufacturers. In fact, one recently launched video game partnered with Mountain Dew, rewarding players with points for drinking more of the soda.

This level of exposure to bromide can be dangerous. Emergency rooms have reported cases of headaches, fatigue, memory loss, and lack of muscle coordination as well as skin ulcers and swelling after extreme bromide exposure, along the lines of 4 to 8 liters of citrus-flavored soda per day. This amount is not atypical for many video-game-loving teens.

Another factor that might demand a second look at an ingredient is new technology that can yield more complete, more accurate toxicity data. One such breakthrough is the Toxicology in the 21st Century, or Tox21 program, a collaboration of the National Institutes of Health, the FDA, and the Environmental Protection Agency. The goal of Tox21 is to improve toxicity assessments in order to rapidly and efficiently predict which compounds can cause adverse health effects in humans. The program uses a high-throughput robotic system to test hundreds of thousands of chemicals using a diverse set of assays. It delivers reliable and reproducible results quickly that can be used to predict toxicity in humans and minimizes animal testing.

But some industry experts believe that rather than wait for lifestyle changes or technology advances to trigger a second look at toxicity, the FDA should have a standing schedule in place to periodically review GRAS substances in light of new technology or new information. Dr. Jacobson shares this viewpoint. "A periodic review, such as every 10 years, would help ensure that GRAS substances are not forgotten about."

PepsiCo announced in January of this year that it would no longer use BVO in its Gatorade as a result of consumer feedback, although they will continue to utilize it in Mountain Dew and diet Mountain Dew. BVO will be replaced by the emulsifier sucrose acetate isobbutyrate, another GRAS substance. ■

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Equipment

MICROBIOLOGICAL ORGANISMS

Alternative Tubing Eliminates Bacteria in Beverage Delivery Systems

Silver lined tubing and fittings, along with replacements to PVC, have the potential to increase quality assurance and improve consistency of product at dispensing | BY **GREG KINNEY**

While the term "antimicrobial" is well recognized in the medical and biomedical fields, it is a relatively new term for the food and beverage industry. Bacteria and biofilm buildup has been a continuing concern from manufacturer to consumer. These microbes originating from natural and external sources contaminate foods by contact, which can occur anytime between production and consumption. Microbial contamination of foods can have many undesirable consequences ranging from spoilage to food borne illness.

Two major concerns for the food and beverage industry in relation to bacteria and biofilm buildup revolve around the consistency of quality control as well as the regulatory environment. This continual battle for producers and dispensers of food and beverage products is evident in the passage and enforcement of laws. A prime example is found in the Connecticut Liquor Control Act. This law dictates that lines used in the dispensing of beer or wine are required to be cleaned once a week. (Sec. 30-6-A.23 (b) Sanitation, pg. 84)

Whether it is dictated by regulations or the need for quality control, a significant challenge for the beverage industry has been to assure adherence to the stringent cleaning standards required to eliminate the buildup of bacteria and biofilm in beverage delivery lines. It is recognized that businesses that dispense their product at the consumer level may not always follow these standards. This biofilm can adversely affect taste and the quality of the product at the consumer level. Because of this reality, the beverage industry has long sought after a solution to help increase consistency and quality of their product between cleaning cycles.

Many in this industry are recognizing that the weakest link in quality control has been in the tubing that transfers and dispenses their product. According to Matt Meadows, national director of field quality for a major craft brewing company in the U.S., the weakest link in quality control is the PVC (poly vinyl chloride) tubing that is used throughout the industry. Meadows states, "PVC tubing has been the weakest link in draught beer system design. Because of the challenges of PVC and the constant buildup of biofilm within the tubing, it is difficult to keep consistent quality from manufacturing to consumer."

Meadows works for one of the largest craft breweries in the U.S. and, like most in the food and beverage industry, it prides itself on quality assurance at every level—down to the final dispensing systems delivering the products. And like most, the company has been hard pressed to find an alternative to the tubing that is currently the industry standard.

After hearing concerns from the food and beverage industry over biofilm buildup, researchers quickly discovered the same innovation that met the high standards for the medical industry could be effective in the delivery and dispensing of food and beverage products as well. The next step was to determine how effective this innovation would be against the bacteria common in these applications.

Antimicrobial Innovations

Initially, innovations in antimicrobial products were driven by the medical and biomedical industries because of the need to eliminate HAI (hospital acquired infections). This same antimicrobial technology is now being applied in everything from consumer products to industrial uses in order to create a cleaner and safer environment.

> The most impressive result is the notable reduction of *Lactobacillus brevis*, which is determined to be the most frequently detected microorganism in beer.

With the information stream constantly flowing from new media, consumers have never been more ready to embrace antimicrobial products. Antimicrobial solutions now go well beyond the medical and biomedical environment. New products are emerging for applications like electronics, apparel/footwear, personal care products, sports/fitness products, and now food and beverage applications.

With these applications becoming more common, consumers are recogniz-

ing there is now technology that is safe to use that can positively impact the things they utilize on a daily basis.

Silver As An Antimicrobial Agent

One of the top innovations is silver, which is a highly effective antimicrobial agent. Silver has long been known for its antimicrobial properties. Recently developed technology now allows for the "smart" release of the silver ions—slow and steady when necessary. This makes it ideal for food and beverage applications where bacteria can thrive.

Elemental ions attack multiple targets in the microbe to prevent it from growing to a destructive population. This tri-modal action fights cell growth in three ways:

- Prevents respiration by inhibiting transport functions in the cell wall
- Inhibits cell division (reproduction)
- Disrupts cell metabolism

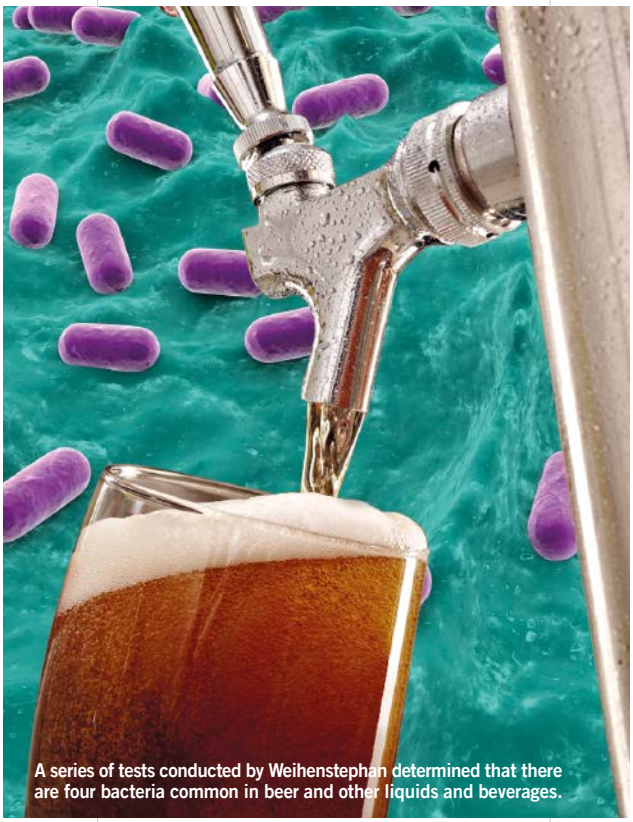
Depending on the microorganism, antimicrobial technology has been shown to initially reduce microbial populate ions within minutes to hours while maintaining optimal performance.

Manufacturing innovations and new developments with polymers that accommodate this smart technology for silver have now made it possible to include this technology in delivery and dispensing systems of food and beverage products. Tubing and fittings are currently being manufactured with a PVC-free polymer that helps eliminate the potential harmful health and environmental effects of PVC coextruded with a silver lining constructed of this "smart" technology.

One such tubing was tested for its antimicrobial properties in beer and water by the Research Center Weihenstephan for Brewing and Food Technology in Germany. The research center, formerly the State Brewing Technology Testing and Experimental Station, was established in its present form in 2004 and is under the direct supervision of the TUM (Technische Universität München) administration. It is an unaffiliated, independent institute, serving the brewing and beverage industries, food producers, associated suppliers, regulatory authorities, and allied trade organizations as a neutral and competent partner.

Weihenstephan conducted a series of tests over several months to determine the antimicrobial activity of existing tubing currently being produced in the U.S. It was determined that there are four bacteria common in beer and other liquids and beverages:

Acetobacter lovaniensis: This acetic acid bacterium occurs in the early stages of biofilm formation. In wort and beer with high oxygen content, acetic acid bacteria can proliferate and cause an acidic off-flavor. It is commonly found on fruits, flowers, vinegars, and in fermented foods and drinks.



A series of tests conducted by Weihenstephan determined that there are four bacteria common in beer and other liquids and beverages.

Wickerhamomyces anomalus (formerly: Pichia anomala): It's frequently associated with spoilage or processing of food and grain products and is widespread among many production steps of alcoholic beverages. It belongs to the group of slow fermenting yeasts and is in carbonated beverages responsible for solvent-like off-flavors. This bacteria was detected in many cases in the brewing environment and its participation in biofilm formation was confirmed.

Lactobacillus brevis: It is by far the most frequently detected microorganism in beer. It's classified as an obligate beer spoiler (i.e. it tolerates all selective characteristics of beer and deteriorates it by haze, acid formation, and off-flavors).

Pseudomonas aeruginosa: This can cause inflammations and infections. It ends up in the brewing environment, especially by the water, and contributes to biofilm formation as slime-forming bacterium. It's a common bacterium that can cause disease in animals, including humans.

The following points summarize excerpts from two recent reports called "Flexelene Silver Tubing Analysis" from the Research Center Weihenstephan.

- Without water flow, the test with the silver lined tubing can be consistently regarded as positive. Despite vast inoculation of bacterial cells well over real contamination cell counts, the silver coating of the tubes was able to reduce the cell count of the four selected microorganisms significantly. The test results confirm that silver lined tubing could diminish the cell concentration of all the tested microorganism species up to 100.0 percent in the 24 hours test period.
- To determine whether taste can be detected in the tubing, a concentrate test was conducted called, "The influence of rubber material to smell and taste" (acc. to MEBAK IV, 2nd edition, issue 1998, "4.6 influence of rubber materials to smell and taste"). It was concluded that there is no significant difference on taste between the "treated" and the blank sample.
- After a circulation of 2,000 liters of water through the tubing, a positive result could be obtained as well. Considerable activity revealed through the tests against *Lactobacillus brevis* (the

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SOURCE: ELDON JAMES

(Continued from p. 35)

most frequently detected microorganism in beer), *Acetobacter lovaniensis*, and *Pseudomonas aeruginosa* where the cell concentrations could be reduced up to 100.0 percent in the 24 hours test period. The antimicrobial activity against the yeast *Wickerhamomyces anomalus* was, in two of three tests, slightly weaker, but still showed a reduced concentration.

- Even after a water throughput of 10,000 liters, the tubing showed positive antimicrobial activity against the acetic acid bacterium *Acetobacter lovaniensis*.
- To address potential concerns of the silver leaching into the flow path, testing was conducted after 2,000 liters, 10,800 liters, and 40,000 liters of water circulation. The analysis concluded that the flow directed through the silver lined tubing had no detectable silver traces in the water (detection limit of the method: 0.01 mg/l).

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Overall, it was determined that the silver lined tubing was 100 percent effective against the top four beverage spoiling bacteria and was successful in reducing the concentrations of three of those bacteria in up to 2,000 liters of flow and *Lactobacillus brevis* up to 10,000 liters. The most impressive result is the notable reduction of *Lactobacillus brevis*, which is determined to be the most frequently detected microorganism in beer.

The Food & Beverage Industry

With the issues facing quality assurance stemming from PVC tubing and biofilm buildup in food and beverage applications, solutions are coming from an industry that is familiar with high-quality standards—the medical industry. Innovations such as silver lined tubing and fittings along with excellent alternatives to PVC have given the food and beverage industry an opportunity to significantly increase and control quality from production all the way to the consumer.

As consumers become more educated on the health issues posed from bacteria along with a better understanding of antimicrobial products, manufacturers and dispensers will both be able to take advantage of these new innovations. ■

Kinney is the director of food and beverage for the Eldon James Corp. He has worked in the beverage industry for over five years with a focus on beer and wine distribution. Leading the food and beverage division, Kinney develops new products that benefit the industry as a whole. He can be reached at 970-667-2728.

Which Measuring Device is Better Suited for 'Soft Solids?'

Exploring the roles of viscometers versus texture analyzers in measuring 'soft solid' materials | BY **ROBERT G. MCGREGOR**

Brookfield Engineering Laboratories recently conducted live interviews with industry experts via its www.TextureAnalysis.com platform to discuss how to measure "soft solid" materials for flow behavior. This category of product is typified by dairy items such as tub butter, margarine, yogurts, ice-cream, and whipped cream. The same conversation could apply to viscous beverages like smoothies and thick shakes. Chocolate could fall into both categories, depending on whether it is a sauce, a filling, or a candy. These everyday products are known as "soft solids" to food scientists. When at rest, which is most of the time, they don't move. They hold their position. Their structure seems to be that of a solid. But once movement takes place, they may be able to flow in liquid-like fashion. So what category of flow behavior do you put these materials into?

Pondering this a bit further raises the basic question of when to use a viscometer versus when to use a texture analyzer. The viscometer assesses flow behavior. The texture analyzer measures deformation and the associated force that causes that change in appearance. Do you need to use both devices to get an integrated piscture? It's an interesting topic and one which food industry manufacturers think about quite often.

Viscometers

Rotational viscometers feature standard disc-type spindles immersed in the fluid and rotated at a fixed speed. The instrument measures torque, or resistance to spindle movement, and that number is converted into viscosity in units of centipoise (cP) or milli-Pascal seconds (mPa.s) outside the Americas (fortunately 1cP = 1mPa.s). Some viscometers also come equipped with a temperature probe since viscosity is directly affected by variations in temperature. The important information to note when making a viscosity measurement includes:

- Spindle type and dimensions (geometry)
- Rotational speeds of spindle used to make the measurement
- Torque in percent of instrument's full scale measurement range
- Viscosity in cP or mPa.s
- Sample temperature
- Elapsed time of spindle rotation when measurement is recorded

R&D personnel have used substitutes for the disc-type spindle to give more accurate and complete viscosity information about the flow behavior of soft-solid materials. There are several alternatives. The T-bar was invented to cut through paste-like materials while moving downward into the sample; this assures that fresh product is measured with each rotation of the spindle. Vane spindles became popular because they insure that heterogeneous materials with particulates are

(Continued on p. 38)

Figure 1: Viscosity Test on Chocolate with Coaxial Cylinder Geometry

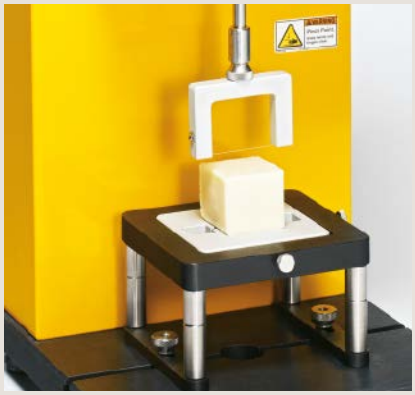

Figure 2a: Wire Probe

Figure 2b: Spreadability Fixture

SOURCE: BROOKFIELD ENGINEERING

(Continued from p. 37)

measured as a mixture; the traditional disc-type spindle may measure only the liquid carrier viscosity. The spiral adapter simulates an augur and, by running at different speeds, can provide viscosity versus shear rate profiles that are not possible with the T-bar, which is really a single viscosity data point tool.

One capability of viscometers, not widely used, is to analyze the viscosity data to derive the yield stress for the material. This is the amount of force required to initiate flow. Chocolate manufacturers test the melted liquid in a coaxial cylinder system that controls temperature while shearing the material at different rotational speeds. See Figure 1. The viscosity data includes shear stress and shear rate values that are plugged into a Casson math model to generate a flowability index and the yield stress for the chocolate sample. These two numbers are sufficient to characterize the chocolate for acceptability in terms of stiffness and flow behavior.

Texture Analyzers

In order to penetrate into a material, texture analyzers use probes of different shapes and sizes (cylinders, cones, balls, blades, etc.). Similar to the viscometer with its controlled rate of rotation, the texture analyzer displaces or cuts into the sample material at a defined rate of penetration (mm/sec) up to a specific distance (mm) and measures the force of deformation (grams or Newtons). The instrument can also measure the pulling force exerted on the probe during retraction from the sample, which is an indication of the material's adhesive property. Some key points to note when using a texture analyzer include:

- Shape and dimensions of the probe
- Speed of probe descent into the material
- Distance of penetration
- Force measurement in g or N
- Rate of retraction from the material

Both instruments clearly give numbers that quantify viscosity and textural properties for soft solids. Does one have an advantage over the other? The test in both cases can be relatively quick, easy to set up, and provide a valid means for QC to approve or reject a component material or finished product. Some soft solids may actually benefit from being tested by both methods in a lab that has done a thorough investigation. Most important, however, is to devise a test which mimics the way in which the end user will use the material. This is the key to assuring consumer acceptance.

Stick margarine can be solid-like when taken out of the refrigerator. A cutting test with a blade or wire makes good sense. See Figure 2a. Tub margarine, by design, should be softer by comparison and more pliable. A spreadability test with cone fixtures will provide a good indication. See Figure 2b. The margarine is placed in a cone-shaped well and a cone probe descends into it to measure the margarine's resistance to being sheared, which is like a spreading action. So the texture analyzer seems to be the better choice for these two soft solids as far as the consumer is concerned.

Processing the margarine before it turns into sticks and tubs poses a different challenge. The material is in a liquid state and needs to be checked for consistency. In this case, the viscometer is the correct tool because it analyzes the margarine's flowability. Margarine, therefore, is a product which can benefit from both types of measurement.

Bottom line recommendation for proper assessment of soft solids is to review both the processing requirements on the production floor and the subsequent ways in which the end user manipulates the product. Knowing these details will lead to the most practical way to conduct testing in the QC lab. Chances are that both the viscometer and the texture analyzer have a bonafide role to play. ■

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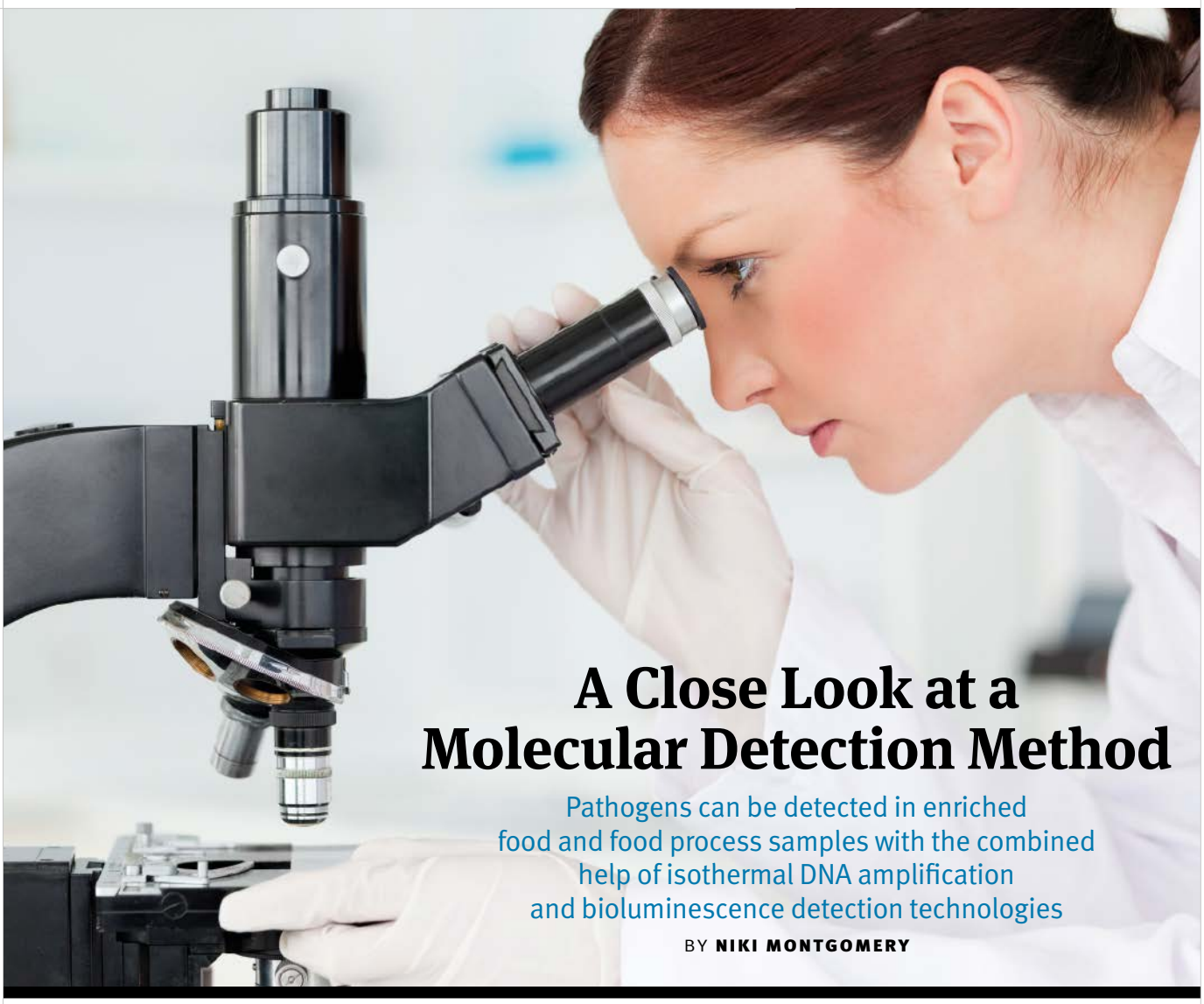

A Close Look at a Molecular Detection Method

Pathogens can be detected in enriched food and food process samples with the combined help of isothermal DNA amplification and bioluminescence detection technologies

BY **NIKI MONTGOMERY**

It's hard to ignore the extreme danger that foodborne pathogens pose to human health; the high amount of Americans getting sick from foodborne diseases says it all. The threats these bugs present to businesses are similarly serious, but are more often overlooked. Economists forecast that pathogens cause between $10 and $83 billion dollars in annual losses worldwide. Clearly, the damage a brand suffers by being associated with an outbreak can be irreparable.

In 2009, 3M started a collaborative research process to understand the largest "pain points" its users were experiencing day in and day out. It consisted of 3M Food Safety experts speaking with food processors across different industry segments, from both developed and developing nations.

Themes of simplicity, speed, and efficiency in addition to accuracy ranked high on their wish-list of new tools that could be employed by their labs, whether it be internal food testing labs or outside reference labs. Users wanted to deploy detection technologies that were accurate, but also low maintenance. The tools would need to quickly spot pathogens in ways that were intuitive and contained fewer transfer steps that might compromise testing accuracy.

Molecular Detection

The 3M Molecular Detection System was conceived as a molecular microbiology approach that could detect pathogens from food samples and samples taken

from processing environments. The system is based on a combination of two technologies: Isothermal DNA amplification and bioluminescence detection. These two "pillar" technologies work together to provide a molecular detection method that is pure and simple. Users only need an enriched sample, a standard laptop, and the 3M Molecular Detection Instrument, a small peripheral device that has a footprint the same size as a tablet computer. Corresponding pathogen-specific assays, or test kits, are also available specifically for identifying the unique characteristics of *Salmonella*, *E.coli* O157 (including H7), and *Listeria*.

With these components in place, users can run and read tests for multiple organisms in a single run with only two transfer steps after the samples have been enriched, which saves hours of technician time. They only need to power up their hardware, transfer enriched samples to the pre-filled, color-coded lysis tube rack, and then place the rack on the provided heating and cooling blocks. Once complete, the users transfer the lysed samples to special reagent tubes that are set inside the instrument via a 3M Molecular Detection Speedloader Tray. From there, they can press start to begin the real-time amplification and detection process.

The Science

To understand the science behind the 3M Molecular Detection System it helps to describe each part of the technologies—isothermal DNA amplification and bioluminescence detection. In terms of amplification, the system identifies and targets multiple regions of a genome through loop-mediated isothermal DNA amplification—commonly known as LAMP for short. An emerging method for rapid molecular detection, LAMP has now been cited in nearly 1,000 scientific articles and has been recognized for its ability to reliably and efficiently target DNA compared to conventional Polymerase Chain Reaction (PCR) methods. For example, whereas PCR typically requires multiple steps for reagent preparation and DNA extraction, the 3M Molecular Detection System uses prefoiled, ready-to-use reagents and only requires two transfer steps with no separate extraction. More importantly, there is no time-consuming thermal cycling involved as in PCR. The system reaction operates at a consistent temperature of 60 degrees Celsius, and the targeted DNA is amplified continuously and as many as one billion copies of DNA can be generated in 15 minutes.

The system identifies and targets multiple regions of a genome through loop-mediated isothermal DNA amplification.

To read and report the DNA amplification taking place, the 3M Molecular Detection System uses bioluminescence technology that works simultaneously in real-time with the amplification. This enzymatic process occurs in two steps: First, pyrophosphate molecules are exponentially generated during DNA amplification and converted to Adenosine Tri Phosphate molecules, or ATP. Second, the system then uses a special temperature-stable luciferase, an enzyme best known for being present in fireflies, to convert that ATP into light. This light, or bioluminescence, is read by the instrument and used to determine the presence or absence of the organism being tested for in the sample.

The end result is a streamlined and automated method of pathogen detection with resistance to sample interference. Third-party validation bodies both inside and outside the U.S. have been consistently examining and validating the Molecular Detection System and its various assays. Companies are also putting the technology to the test with their food matrices. Based on the feedback received, the method is not only highly accurate, but good for business operations given that only one preparation protocol is necessary for all pathogens and matrices, and that batch-processing and simultaneous testing can happen for multiple pathogens. ■

Montgomery has more than 15 years of experience at 3M in quality control and operations, marketing, channel management, and finance. She can be reached at nmmontgomery@mmm.com.

The 3M Molecular Detection System is a molecular microbiology approach that has the ability to detect pathogens from various food samples.

Students expand their knowledge and expertise in a HCAS classroom.

Specialized Materials Analysis Training Pinpoints and Corrects Hazards

As the FDA decides whether it should mandate training for employees and supervisors, food quality professionals need to know what type of training programs will meet the requirements | BY **CHARLES ZONA** AND **CHERYL MURLEY**

The June 2012 passage of the FDA's Food Safety Modernization Act, or FSMA, will soon require preventive controls for companies that manufacture, process, pack, or hold human food. These companies will be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures, record monitoring results, and specify what actions will be taken to correct problems that arise. These actions were initiated to prevent problems that can cause foodborne illness, but a frequent risk in the food industry is the presence of foreign material from ingredients, processing equipment, and the environment. Although the proposed rule aligns well with Hazard Analysis and Critical Control Points (HACCP), it differs in that preventive controls may be required at points other than at critical control points, and critical limits would not be required for all preventive controls.

To establish the correct preventive measures and develop a successful program that withstands FDA scrutiny, food quality employees need specialized materials analysis training that enables them to characterize and identify raw material and processing contaminants and their sources.

Specialized Materials Analysis

The presence of foreign material from ingredients, processing equipment, and the environment is a frequent risk in the food industry. Foreign material can be a risk in and of itself, or it can be the source of foodborne illness (microbiological contamination), and can provide clues to the source of contamination. Well-trained quality employees can easily compare suspect contaminants to reference samples from the manufacturing process and eliminate or confirm suspects based on appearance. This type of training can also be advantageous when addressing customer complaints for foreign matter contamination; successful identification of foreign matter is instrumental in determining the validity of complaints and developing the corrective actions needed.

Courses on materials identification can train food quality professionals to identify the specific hazards for their facility or industry so they can ensure that preventive controls are appropriate for the risk and not over-engineered. For example, incompatible gasket materials commonly cause contamination in the food processing industry. Identifying the offending material so it can then be replaced with a more compatible material is a simple step and is an easier solution than installing filters or screens downstream and implementing routine QC checks of those controls.

Food quality employees regularly attend microscopy courses at Hooke College of Applied Sciences (HCAS) with the goal of becoming proficient in the identification of food contaminants, in particular, contamination from extraneous materials and particles.

All-Inclusive Engagement

Learning to use specialized equipment such as research-grade microscopes

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can be challenging, especially if the microscope brand or model used in the classroom differs from the equipment at your workplace. HCAS has found that using a blended learning approach—one that augments classroom training with distance learning from the student's lab—is an advantageous approach for students.

A study by the U.S. Department of Education's Office of Planning, Evaluation and Policy Development's Policy and Program Studies Service recognized that blended learning produced a larger advantage in learning outcome relative to purely face-to-face instruction than did purely online instruction. This study focused mainly on post-secondary and adult learners.

At HCAS, blended learning begins with pre-course online content consisting of both narrated learning modules and fully functional virtual microscopes. The narrated modules are 25 to 35 minutes long. The microscope simulations offer virtual versions of the instruments used during the course, allowing students to review the parts of the microscope, build the microscope from its virtual parts, and engage all of the microscope parts, simulating the microscope's function.

The hands-on portions of the courses are taught as three-day or four-and-a-half-day sessions, which follow a traditional classroom format. Each student has access to a microscope during class and is expected to successfully complete a variety of tasks related to the lecture material presented in the course. Tasks include hands-on practice, laboratory exercises, identifications of unknowns, and competency checks. Students are required to have 100% attendance during the course, participate in class, complete a student evaluation form, and complete a pre-course and post-course knowledge and skills assessment form.

Each course is primarily taught by HCAS faculty, who are all members of McCrone Associates' technical staff. McCrone Associates is a microscopy laboratory, pioneering innovative particle identification and materials analysis methods. All instructors currently work in laboratories where they use the techniques they teach to the students.

Techniques learned during training can be basic, such as the use of the stereomicroscope or polarized light microscope to get a better view of contaminants for basic characterization purposes. Is the contaminant glass, metal, or plastic? Does the material look corroded or thermally degraded? This will narrow down the detective work needed and allow the investigator to collect the appropriate reference materials from the manufacturing process to compare against the unknown sample. A contamination source can possibly be identified without definitively naming the components of the offending material. The techniques can be complex, such as the use of Fourier transform infrared spectroscopy (FTIR) to identify thermally degraded sugar or starch compounds, or the use of scanning electron microscopy (SEM) to determine the type of metal.

After the classroom portion of the course, students login to access a live, online, instructor-led session, where they discuss unknown samples that were sent to their labs by the instructor. Post-course sessions offer students an opportunity to put into practice the skills learned during the course, while using the equipment available to them at their facilities. Sessions allow participants with little experience to build confidence, while those with more experience can share insight with their less experienced colleagues. During this final web-based portion of the course, students begin the process of self-directed learning and inquiry, reinforcing the acquired concepts and skills learned earlier in the pre-course modules and in the classroom. The post-course environment encourages the exchange of ideas, such as alternative techniques and approaches used for identifying the unknowns. In addition, students are encouraged to analyze samples brought from their workplace during the hands-on portion of the class.

It's important to receive training from an International Association for Continuing Education and Training (IACET) Authorized Provider. Organizations like HCAS offer CEUs for its programs that qualify under the American National Standards Institute (ANSI)/IACET Standard, which is widely recognized as the standard of good practice internationally. The requirements set forth by IACET create transparency in course structure, enabling learners to know who is teaching their course, the instructor's experience level, the type of equipment to be used in class, and the expected student learning outcomes upon completion of each course.

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When choosing a training provider, choose a materials analysis course that trains quality professionals not only within a specialized academic environment, but also with an online component to be carried out in the student's own laboratory with materials specific to their industry. Ask questions to determine the instructor's experience level, the age and type of equipment being used in the classroom, the types of learning resources available, and the material expected to be learned upon completion of the course. Ensure your training choices have sufficient credibility to withstand regulatory scrutiny. ■

Zona is the dean of Hooke College of Applied Sciences, Westmont, Ill. **Murley** is the quality manager at McCrone Associates, Westmont, Ill.

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Five Essential Tips for Effective Sanitation

New and old employees should be aware, or reminded, of the fundamentals for controlling the risk factors associated with food contamination | BY **LORI VALIGRA**

For microbiologist Jeff Kornacki, PhD, danger lurks around the corner in every restaurant and supermarket he visits. The food safety consultant admits that he eats at fast food restaurants, but with some trepidation. And as much as he tries to avoid looking at the kitchen as he waits in line, he says he can't help himself. "I've seen people making sandwiches reach into one set of ingredients and then another—olives, lettuce, pickles, and they're handling it all," says the head of Kornacki Microbiology Solutions Inc. in McFarland, Wis. "They have plastic over their hands and are wiping off counters with a wet cloth that has been around all morning. And if they don't change their gloves, they've transferred a vast population of microbes from the cloth onto the food."

And that's just one link in the chain of people from farmers to food servers who potentially could contaminate food. Most of the foodborne illnesses experienced today are preventable if farmers, chefs, food processors, cooks, and servers focus on safety, according to the Center for Science in the Public Interest, a nonprofit consumer group.

The Food Safety Modernization Act (FSMA) aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. The FDA recently proposed two major rules for the Act regarding preventive controls in human food and produce safety. While the Act focuses on farms and processors, its benefit filters down to restaurants and supermarkets in the form of potentially improving the safety of meat and other foodstuffs moving through the food chain, says Sarah Klein, senior staff attorney for the Center for Science in the Public Interest's Food Safety Program. Other standards also are being upgraded, including the American National Standard for Bakery Equipment Sanitation Requirements (see sidebar).

Sanitation in Food

There are three main types of hazards or contaminants that can cause unsafe food: Biological, chemical, and physical. Biological includes microorganisms; chemical includes cleaning solvents and pest control; and physical means hair, dirt, or other matter.

In our research, we've come up with five frequently mentioned sani-

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tation tips to prevent foodborne illnesses in food service and retail businesses. They are:

1) Proper personal hygiene, including frequent hand and arm washing and covering cuts;
2) Proper cleaning and sanitizing of all food contact surfaces and utensils;
3) Proper cleaning and sanitizing of food equipment;
4) Good basic housekeeping and maintenance; and
5) Food storage for the proper time and at safe temperatures.

Proper employee education and training, as well as monitoring and record-keeping by management of clean and sanitation tasks, also are important, according to Joshua Katz, PhD, new director of the Food Marketing Institute's Food Safety Programs in Arlington, Va.

But while procedures and training can be put in place, their effectiveness depends on how they are enforced. One way is to apply public pressure to those with cleanliness issues, says Klein. "The Center for Science in the Public Interest makes the results of the health department inspections more public. We believe the transparency of those results...will serve as an incentive."

Klein says restaurants need to bear some responsibility for the periodic training of employees and oversight. "They need to ensure materials that explain the responsibilities of employees are available to them in multiple languages, English, Spanish, Chinese, and that there are visual cues, such as hand washing signs above the wash sink." Some chains, such as Clyde's Restaurant Group, have periodic hand-washing competitions as a built-in incentive for cleanliness, she says. One company that is known for its sanitation controls is McDonald's, adds Klein. "Those types of entities are keeping control of their brand."

While there are no national food safety standards that can be imposed on restaurants and supermarkets serving food, Klein would like to see a mandatory nationwide adoption of the most recent FDA Food Code (2009).

#1 Tip: Personal Hygiene

Most foodborne illnesses are caused by bacteria or other microorganisms spread by people who handle food, according to a report called "Serving it Safe" from the National Food Service Management Institute and the U.S. Department of Agriculture. The report also noted that every action in food service could potentially impact food safety during purchasing, storing, preparing, holding, serving, or cleaning.

Perhaps the most basic step toward safe food is teaching restaurant, supermarket, and other food-handling staff the importance of basic hygiene. That includes washing their hands and exposed arms frequently and at key times in food handling, such as when they switch from touching raw to cooked food. Covering cuts also is critical.

The FDA's 2009 Food Code cleaning procedures recommend that food employees clean their hands and the exposed portions of their arms, including prosthetic devices, for at least 20 seconds using a cleaning compound in a hand washing sink. To avoid recontaminating their hands or prosthetics after washing, employees should utilize disposable paper towels or similar clean barriers whenever touching surfaces such as faucet handles and restroom door handles.

Injuries on the hands or lower arms should be cleaned and treated immediately so they do not become infected and contaminate food and equipment, according to *The Idaho Food Safety and Sanitation Manual*. Rubber or plastic gloves should be worn until the injury is healed and to prevent a bandage from getting into food. In addition, do not wash hands in sinks designated for food preparation or equipment and utensil washing as that can contaminate food, equipment, and utensils.

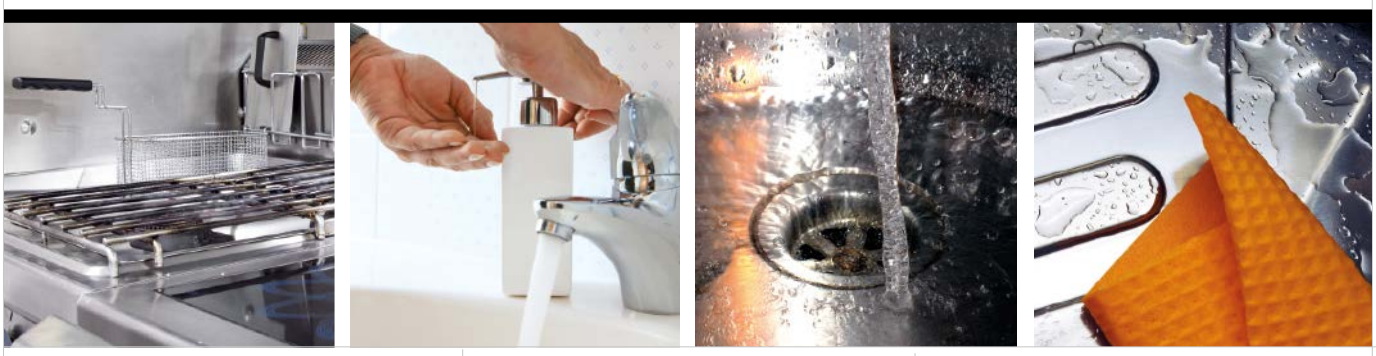
"Training is important," says consultant Kornacki. "Fast food has rapid employee turnover, so you need policies in place and training programs."

#2 Tip: Clean Contact Surfaces

Proper cleaning and sanitizing of all contact surfaces and utensils is a must, according to food sanitation experts, as food can typically get trapped in places like counter cracks and in between fork tines.

Unsanitary facilities and equipment may spread harmful organisms to people or food, according to the "Serving it Safe" report. Also, cockroaches, flies, mice, and other disease-spreading pests seeking food could contaminate food, equipment, or service areas.

The report also warns against preparing raw meat and raw fruits or vegetables on the same surface at the same time to prevent cross contamination and microbial transfer. This means avoiding



cleaning or cutting raw chicken on the same surface as lettuce.

#3 Tip: Sanitizing Equipment

Food equipment such as slicers and fillers can be difficult to clean, especially the internal parts where a piece of meat could get stuck and become a hotbed for bacterial growth.

"There are going to be pieces of equipment that need to effectively be taken apart to a certain degree to clean them," says Kornacki. "Equipment sometimes isn't designed to be cleaned and sanitized efficiently." He notes that he has spent more than six hours merely taking a slicer apart.

With high-moisture foods, there are still pieces of equipment that are hard to sanitize such as slicers and fillers, says Kornacki. Dry foods such as walnuts also can be problematic. He says the current challenges may lead to better equipment design going forward.

"Ideally, you'd break down the equipment every day," Kornacki adds. "But you need to balance what is practical with what is effective."

#4 Tip: Good Housekeeping

It's important to apply good basic housekeeping and maintenance to food preparation areas of a store or restaurant. The "Serving it Safe" report notes that food service establishments use various chemicals to clean and sanitize and for pest control, but if not handled correctly they could contaminate food and make people sick, and even injure the employee.

Such hazardous chemicals include sanitizers, pesticides, whitening agents, detergents, polishes, and glass cleaners. The report urges establishments to teach employees how to use chemicals properly, store chemicals in their original containers away from food, make sure they are clearly labeled, and to use materials safety data sheets to assure they are stored and used correctly.

#5 Tip: Safe Storage

To keep bacteria and other microorganisms from growing, it is important to store food at the correct temperature for the proper amount of time. Microorganisms are more likely to grow in the danger zone where the internal food temperature is between 41 degrees Fahrenheit and 135 degrees Fahrenheit, according to the "Serving it Safe" report.

The report recommends that a food service operation document temperatures and keep written procedures at each stage of food production to make sure the time-temperature requirements are met.

"One of the things we're seeing, especially with meat and poultry, is contamination after cooking," says Klein. This is true if food is out set too long, or if it is cooked in advance. "A chicken may be cooked to 165 degrees, but if the internal temperature drops sufficiently, bacteria can grow," she says of ready-made food that may linger in a warming tray for hours.

At the same time, where food is stored is important to prevent cross-contamination. The "Serving it Safe" report notes that a common mistake is to leave thawing meat on the top shelf in the refrigerator where it can drip onto foods below. Finally, it's important to not cool food items in the same ice that will be consumed in food and beverages. ■

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Bakery Sanitation Standard Focuses on Improved Equipment Design

Despite zealous efforts to clean the visible surfaces of bakery equipment, residual food and other particles can get stuck in hard-to-reach areas. They, in turn, can become moist breeding grounds for pathogens that risk food safety.

Improved equipment design that is easier to break down, clean, and maintain may reduce the risk of foodborne illness outbreaks and product recalls, according to sanitation experts. In an effort to address the issue, the American National Standards Institute last October approved the 2012 version of the American Society of Baking's ASB Z50.2 American National Standard for Bakery Equipment Sanitation Requirements. The standard sets parameters for the sanitary design, construction, and installation of improved bakery equipment.

"The baking industry needs to be forward-thinking in the design of its equipment and the ability to effectively and efficiently clean production equipment," Robb Mackie, president of the American Baker's Association, said in a statement when the new requirements were approved.

Reducing Risk of Microbial Contamination

High-quality microbiology equipment and supplies meet the demands for producing rapid, accurate results for today's labs

By **Marian Zboraj**

IT SEEMS THE MAINSTREAM MEDIA'S ATTENTION on the food industry gets more critical with each new headline, making the issue of ensuring food safety more important than ever.

"With bacterial outbreaks in the food industry, microbiologists have looked for alternative methods in quality control," comments Sinderella Abdallah, microbiology product manager at Advanced Instruments, Inc. "With that in mind, the market has developed various systems, varying in speed and accuracy, to aid microbiologists."

Doris Engesser-Sudlow, diagnostics global director at DuPont Nutrition & Health agrees. "Increasing regulatory requirements for controlling pathogens, such as for STEC in the U.S. or *Salmonella* serotypes in Europe, are driving an increased use of rapid testing methods." Engesser-Sudlow explains food companies are looking at every step of their process, including improving shelf life, sample collection, automation, reduced labor cost, and testing accuracy.

Luckily, companies like Advanced Instruments, DuPont, and others are answering the call to provide diverse solutions for food companies. For instance, Advanced Instruments' Autoplate Spiral System provides a reduction in costs by eliminating up to 75 percent of materials required with serial dilutions by providing a 4-log dilution effect across a standard plate in a 35 seconds cycle time. Meanwhile, Roka Bioscience offers an all-in-one molecular pathogen detection design. Its Atlas system can save valuable bench space and eliminate the need for additional equipment, like centrifuges or biological safety cabinets. TandD ensures users don't have any gaps in data collection with its wireless instruments that deliver error-free record keeping. And besides food diagnostic systems formerly available under the Qualicon name, DuPont Nutrition & Health also offers its DuPont Danisco range of ingredients to provide enhanced protection against unwanted microbes and other benefits.

With the spotlight put on food contamination as of late, laboratories can rest assured there are comprehensive solutions available that have the capability to meet all their microbial testing needs and ensure their products don't make headlines for the wrong reasons. ■

Zboraj is Editor of Food Quality.

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IN FOOD QUALITY & SAFETY

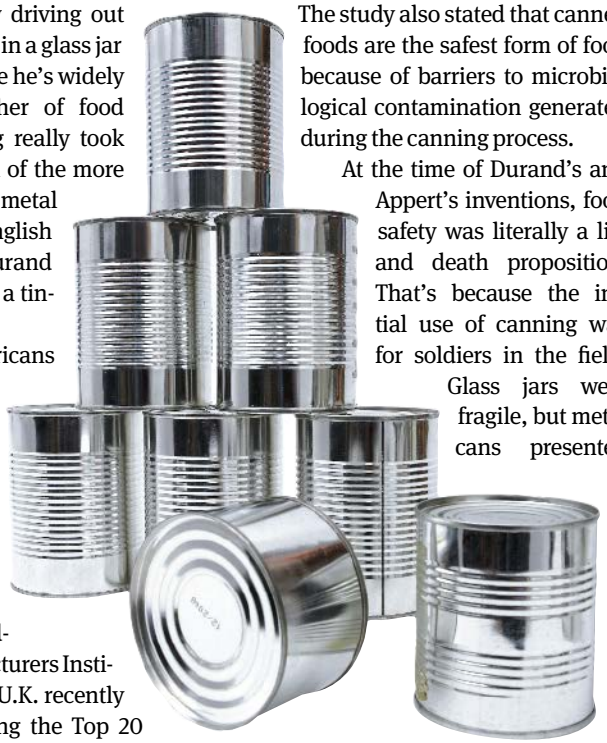
Peter Durand's Metal Can Led to a Food Safety Staple

BY **LORI VALIGRA**

The ubiquitous can has come a long way since 1795 when Napoleon offered a 12,000-franc prize to anyone who came up with a food preservation method that would assure his men had safe rations. Parisian confectioner Nicolas Appert claimed that prize by driving out air and heat from food in a glass jar before sealing it. While he's widely regarded as the father of food preservation, canning really took off after the invention of the more practical and durable metal can in 1810, when English merchant Peter Durand got the first patent for a tin-plated container.

Nowadays, Americans use more than 100 million metal cans a day in 600 different sizes and styles. Of the 131 billion metal cans produced each year, some 26 billion are used for food preservation, according to the Can Manufacturers Institute. Scientists in the U.K. recently ranked canning among the Top 20 food and drink innovations of all time just behind refrigeration and pasteurization/sterilization, according to the *Daily Mail* newspaper.

In fact, canned foods help with food safety, as stated by a May 2012 Michigan State University study that analyzed more than 40 scientific journal studies comparing canned fruits and vegetables to fresh and frozen. "Depending on the commodity, freezing and canning processes may preserve nutrient value, and while canned foods are often regarded as less nutritious than fresh or frozen products, research reveals that this is not always true," Michigan State University authors Steven Miller, visiting instructor, and Bill Knudson, professor, concluded. The study also stated that canned foods are the safest form of food because of barriers to microbiological contamination generated during the canning process.



At the time of Durand's and Appert's inventions, food safety was literally a life and death proposition. That's because the initial use of canning was for soldiers in the field. Glass jars were fragile, but metal cans presented their own challenges. Because the can opener wasn't invented until 1855, soldiers opened early cans with bayonets or smashed them with rocks.

The first Durand patent granted by King George III of England in 1810, and which was re-filed in the U.S. in 1818, was for a method of preserving animal, vegetable, and other perishable foods using vessels made of glass, pottery, tin, and other metals, though Durand focused only on the tin can to improve on Appert's glass storage. The procedure involved filling a can with food, raw for vegetables and half-cooked or raw for meats, and capping it. The filled can could then be heated in an oven, stove, or steam bath, or immersed in water and then boiled. During the heating and subsequent cooling procedure, the cap was left partly open, but immediately afterward it was sealed airtight by a cork, screw cap with a rubber seal, or a cemented cap.

Durand does acknowledge in his first patent that he got the idea for the invention more than a year earlier from a friend abroad, who is thought to have been French engineer and inventor of the first flax spinning frame, Philippe de Girard. The Frenchman demonstrated canned foods at the Royal Society in London. Durand's patent describes both the original idea and observations by Durand, who tested the concept thoroughly by sealing meat, soups, and milk and boiling them using the method. The original inventor had tested only small volumes of food, but Durand had expected large-scale production in the future and preserved up to 30 pounds of meat in one can. He also tested the canned goods with the Royal Navy for four to six months, and reports by members of the Royal Society and Royal Institution said the food was preserved.

Durand didn't develop the patent, rather he sold it for 1,000 pounds to two Englishmen, Bryan Donkin and John Hall, in 1812. The two tested the preservation concept then set up a commercial canning factory and produced the first canned goods for the British army and navy in 1813. Like the incentive from Napoleon to have safe food for his troops, Donkin and Hall aimed to have the British military travel farther and longer on their provisions. By 1818, the Royal Navy used up to 24,000 large cans on its ships each year, according to the Can Manufacturers Institute. Sailors previously had to rely on live cargo or salted meat, but now had canned vegetables as well. The concept of canned food spread throughout Britain and France before arriving to the U.S. in the early 1820s. ■

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From 35 mL to 2,400 L — Eppendorf has you covered

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> The DASGIP line of bioreactors ranging from 35 mL – 3.8 L, with parallel control of up to 32 vessels simultaneously, perfect for high throughput processes

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