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BIO-RAD

From The Editor

In early May, Vermont Governor Peter Shumlin signed into law HB 112, a bill that would require mandatory labeling of foods containing genetically modified ingredients in Vermont. While consumer advocacy organizations are praising the nation's first GMO labeling law, industry food groups like Grocery Manufacturers Association (GMA) are challenging the bill, claiming it's critically flawed.

In light of this labeling debate, the International Food Information Council (IFIC) recently released the results of its 2014 "Consumer Perceptions of Food Technology" survey. According to the survey, 63 percent of consumers are content with current labeling policy for foods produced with biotechnology, which calls for labeling only when biotechnology substantially changes the food's nutritional content/composition or if there's a potential safety issue. The survey shows that only 4 percent wanted information about biotechnology or related terms.

Many consumers also report they're likely to buy foods produced through biotechnology to obtain certain benefits. For instance, more than two-thirds of Americans say they'd likely purchase foods made with biotechnology to reduce the potential for carcinogens (69 percent), be protected from insect damage and require fewer pesticide applications (69 percent), enhance nutritional benefits (67 percent), and eliminate the trans-fat content in foods (67 percent).

"When consumers understand the potential benefits that technology in food production can have for both people and the planet, they can get behind it. People need to know what's in it for them," says Marianne Smith Edge, MS, RD, LD, FADA, FAND, senior vice president of nutrition and food safety at IFIC.

"GM crops are safe and have important benefits for people and our planet," according to a statement from GMA. "They use less water and fewer pesticides, reduce crop prices by 15 to 30 percent, and can help us feed a growing global population of seven billion people." The organization points out consumers who prefer to avoid GM ingredients can buy products already labeled "certified organic."

But Vermont Attorney General William Sorrell has begun the process of drafting rules to implement the new Vermont law. The Attorney General's Office is soliciting input from the public, including food processors, grocers and other retailers, the agricultural community, and consumers.

Wanting to avoid a "50-state patchwork of GMO labeling policies," GMA is pushing for bipartisan federal legislation, the Safe and Accurate Food Labeling Act, HR 4432, which would require a label on foods containing GM ingredients only if the FDA determines there is a health or safety risk. This would help ensure food labels are accurate and consistent, eliminating consumer confusion.

Marian Zboraj
Editor

Food Quality & Safety
FARM TO FORK SAFETY

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NEWS & NOTES

Organic Fertility Research Project

The LSU AgCenter and the New Orleans Ernest N. Morial Convention Center recently held a ribbon-cutting ceremony to celebrate LSU AgCenter's organic fertility research project, located on property near the convention center. For the next two years, research on Bella Rosa tomatoes will be conducted on the one-quarter acre plot to evaluate the effectiveness and economics of organic fertilizer versus conventional fertilizer used in vegetable gardening, to monitor disease, and to study the microbial qualities of irrigation water over the growing season. The tomatoes will be harvested in June, and a preliminary report of the findings will be presented at the 2nd Annual Farm to Table International Symposium at New Orleans' convention center in August.

Controlling *Listeria* in Delis

The FSIS released its "FSIS Best Practices Guidance for Controlling *Listeria monocytogenes* (Lm) in Retail Delicatessens" that discusses steps retailers can take to prevent listeriosis associated with the consumption of certain ready-to-eat foods that are prepared or sliced in retail delis and consumed in the home, such as deli meats and deli salads. FSIS encourages retailers to review the guidance and evaluate the effectiveness of their retail practices and intervention strategies in reducing the risk of listeriosis to consumers from these meat and poultry deli products. The agency will consider all comments submitted and will revise the best-practices guidance as necessary.

Laundry Certification for Food Manufacturing/Processing

Developed from TRSA's Hygienically Clean for Healthcare, the new Hygienically Clean Food Safety program emphasizes best practices for laundry processes and quality control practices verified through facility inspection and microbial testing of reusable textiles. Verified laundry practices include washing procedures (detergent formulas, temperature, disinfectant, pH, extraction), drying, garment inspection, and transportation. A certified laundry plant must follow an operational flowchart that maps these procedures as well as pickup, unloading and sorting of soiled items, and sorting of clean laundry. Employees' use of personal protective equipment must be documented. HACCP practices will also be examined.

Food Ingredient Safety Research

The food, beverage, and consumer products industries, in association with the Grocery Manufacturers Association and Michigan State University (MSU), are partnering to create the Center for Research on Ingredient Safety (CRIS). An independent, academic, science-based center, CRIS will serve as a reliable and unbiased source for information, research, training, and analysis on the safe use of chemical ingredients in consumer packaged goods including foods, beverages, cosmetics, and household consumer products. It will be modeled after already existing centers of expertise at other academic institutions, which focus on allergen and microbiological safety. CRIS will be located at MSU and will be governed by an advisory board composed of multiple stakeholders, including academic, industry, nongovernmental organizations, and regulatory representatives.

Training Food Safety Professionals

The National Environmental Health Association's newest credential is the Certified in Comprehensive Food Safety credential, which was instituted largely as a response of FSMA to educate food safety professionals in the new regulations. Holders of the credential are required to demonstrate expertise in how to assure food is safe for consumers throughout the manufacturing and processing sector. Also, the Certified Professional–Food Safety credential is designed for food safety professionals in both the public and private sectors whose primary responsibility is the protection and safety of food products. The course and exam to earn this credential focuses on topics such as food microbiology, regulatory requirements, and HACCP.

Business Briefs

Intertek opens a new UKAS accredited food laboratory in the U.K.'s Derby, Derbyshire.

Thermo Fisher Scientific opens a new contamination inspection facility in Sunnyvale, Calif.

XL Group's Crisis Management team partners with **The Acheson Group** to help businesses manage complex food safety and regulatory risks.

Ali Group North America creates a new Refrigeration Division to support and promote its two refrigeration brands, Beverage-Air and Victory Refrigeration.

Washington Report

'Doing the Right Thing' to Ensure Food Safety

Incorporate food safety into all aspects of your business or risk becoming a target of FDA's new enforcement powers

BY **TED AGRES**

Senior executives of large food distributors, industry consultants and attorneys, and even FDA officials agree it will take more than simply abiding by the Food Safety and Modernization Act (FSMA) to ensure that unsafe food does not enter the marketplace. "At the end of the day, any regulations, any of your food safety programs, any of your SOPs, are all designed to deliver a specific result—food safety," said Craig W. Henry, PhD, vice president, Decernis LLP.

"The real challenge is fewer foodborne illnesses, higher consumer confidence in the products that are produced and made available to that marketplace, and a higher degree of confidence in those who help govern, manufacture, deliver, distribute, and retail those products," Henry told attendees of a workshop at this year's Food Safety Summit in Baltimore on "Doing the Right Thing—Meeting Consumer and FSMA Food Safety Expectations."

Jorge Hernandez, senior vice president for food safety and quality assurance at US Foods Inc., said safety and quality have to be part and parcel of any business. US Foods has more than 550 private label suppliers from more than 10 countries, and offers more than 300,000 private label and manufactured products. As a result, "the potential for a problem to be exponentially huge [exists] within a matter of days. To me, it's not about regulation, but about doing the right things," Hernandez said.

But for those who fail to grasp the importance of inculcating food safety into every aspect of their business, a senior FDA official outlined the new enforcement powers made available through FSMA, and explained how and when the agency intends to use them. Roberta Wagner, deputy director for regulatory affairs, FDA's Center for Food Safety and Applied Nutrition (CFSAN), told workshop attendees that a key program goal is to develop and swiftly deploy the fastest, most effective methods for identifying, containing, and eliminating food hazards.

Enhanced Records Inspection

The first of the new tools is expanded authority to obtain and inspect food company records. FSMA Section 101 amended Section 414 of the Food Drug & Cosmetics Act, which itself had been added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the BT Act). The BT Act gave FDA access to records relating to food produced by a registered facility that the agency "reasonably believes" to be adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA). FSMA expanded the agency's reach to records relating to "any other article of food" that it reasonably believes is likely to be similarly affected (not including farms and restaurants).

FSMA also gives FDA access to records when it has a "reasonable belief" that an article of food is adulterated, or that the agency believes there is a "reasonable probability" that use of or exposure to an article of food will cause SAHCODHA. "There's a lot of the food industry where the FDA goes out and does inspections and we had absolutely no authority to review certain records," Wagner explained. "We will invoke the use of this authority to gain access to those records."

Having this authority would have been useful during FDA's investigation of the Peanut Corp. of America during the massive *Salmonella* outbreak in 2009. "The firm refused to show us records regarding its testing programs and testing results," Wagner said. "The way the records access

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authority was originally put out there, we were limited initially to only records that pertained to one line in that manufacturing facility, and only the one that produced the King Nut peanut butter that was identified initially as producing several illnesses in a nursing home," Wagner told the workshop. "The authority given to us under the BT Act of 2002 was way too narrow."

The FDA has used its enhanced records access authority several times. During its April 2013 investigation of an *E. coli* O121 outbreak associated with frozen pizza producer Rich Products Corp., Buffalo, N.Y., the FDA obtained records from a different facility that had milled raw wheat and other flour ingredients. The agency also used the expanded authority in October 2013 while investigating a dietary supplement from USP Labs LLC, Dallas, Texas, associated with reports of liver toxicity. "The records access was quite broad in that case as well," Wagner said.

Since 2007, FDA has invoked its records access authorities (under the BT Act and FSMA) 26 times in cases when firms refused to turn over records. Wagner noted that FDA may not need to invoke this authority as much in the future because FSMA Section 103, the Hazard Analysis and Risk-Based Preventive Controls, requires food processors and manufacturers to make their records available "promptly" to FDA upon request.

Suspension of Registration

A more powerful enforcement tool is the suspension of facility registration. FSMA Section 102 allows FDA to suspend the registration of a facility when the agency determines that food manufactured, processed, packed, received, or held has a "reasonable probability" of causing SAHCODHA. Unlike the enhanced records access, a suspension order requires the personal approval of the FDA commissioner. One reason is the provision's implications: A suspension order applies to all operations and facilities associated with a company's registration, not just the one that may be linked to SAHCOHDA. "It has the effect of an injunction," Wagner said, because it prohibits a company from introducing any food into commerce, including items produced before or after the suspension order was received.

FDA has exercised this authority twice. In November 2013, it suspended the registration of Sunland Inc., Portales, N.M., following an outbreak of *Salmonella* in peanut butter that sickened at least 35 people in 19 states. In March 2014, FDA used this authority against Roos Foods Inc., Kenton, Del., a producer of Latin-themed cheese and other dairy products, after an outbreak of listeriosis linked to its soft cheeses products from which one person died and seven others were hospitalized.

"It's typically not one thing that goes wrong that leads to a problem of this magnitude; it's a multiple factors that contribute to a problem of this size," says David Acheson, MD, CEO, The Acheson Group and a former FDA associate commissioner for foods. In the case of Sunland, the FDA had reviewed the facility's internal testing records and found multiple positive *Salmonella* results throughout the plant and in finished product during the previous three years, along with other "serious violations" of current Good Manufacturing Practices. Even though Roos Foods had voluntarily recalled its products, FDA invoked the suspension after inspectors found unsanitary conditions in the facility, including rainwater leaking from the roof onto cheese processing equipment, bags of salt, packaging materials, and pooling on food contact surfaces.

"It's difficult to argue that FDA shouldn't exercise the option for immediate action when food-contact surfaces are being subjected to a 'rain storm' of potential contamination," Dr. Acheson argues in a recent posting.

Mandatory Recall

FSMA Section 206 for the first time gives FDA mandatory recall authority of food products. The threshold is a reasonable probability that food is adulterated or misbranded and evidence that its use or exposure will cause SAHCODHA. A recall order also requires the FDA commissioner's approval. According to Wagner, a mandatory recall comes at the end of a process. The first step is a verbal request to undertake a voluntary recall. If the firm declines, the next step is a 423(a) letter, formally known as Notification of Opportunity to Initiate a Voluntary Recall. "If the firm refuses to do anything after that point, that's where you will get an order to cease distribution and notify customers or conduct a mandatory recall," Wagner said.

While FDA has not invoked this mandatory recall authority, it has issued several 423(a) letters. In 2013, FDA issued a letter to Kasel Associated Industries, Denver, Colo., because of *Salmonella* in its pet food products. The company initiated a voluntary recall. Earlier this year, the agency sent a 423(a) letter to USP Labs over its dietary supplement linked to liver toxicity. USP also conducted a voluntary recall.

If your company is involved in a recall, "your odds of being inspected skyrocket," Dr. Acheson says. "You then better ensure that all your food safety programs including your environmental monitoring, cleaning, and sanitation practices are in top-notch shape, and you identified the root cause of the recall and eradicated it. Otherwise you risk inspectors citing you for insanitary condition violations—which are on the rise."

Administrative Detention

FSMA Section 207 allows for enhanced administrative detention of food, which means FDA can hold adulterated or misbranded food to prevent it from entering the marketplace. The original threshold granted under the BT Act was "credible evidence or information that the food presents a threat" of SAHCODHA. "We never quite met that threshold" to use the authority, Wagner said. Under FSMA, the standard has been expanded to "reason to believe that an article of food is adulterated or misbranded." FDA has invoked this authority seven times since 2011 for fishery products, dietary supplements, and other foods, she said.

But as industry representatives agree, hewing to the regulations alone is not sufficient. "We know that FSMA will have a positive impact on food safety, but it cannot be viewed as a magic bullet," Wagner said. "It will take everyone—food processors, manufacturers, suppliers, third-party auditors and labs, and regulators—acting vigilantly and responsibly to assure that no one segment of the food supply chain or firm is enabling or permitting poor performance, resulting in unsafe food making its way into consumers' homes." ■

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Industry Insights

Agriculture + Chinese Apples = Assurance of Safety?

The concerns surrounding the import of fruit juice ingredients from China | BY **KARLYNN FRONEK**

The growth of U.S. imports from China has exploded over the past five years; apple juice concentrate is a perfect example. Recent statistics indicate that 78 percent of the concentrate we import comes from China. The reason: China grows one-half of the world's crops. That was not always the case. Since China entered the World Trade Organization in 2001, much has changed. Global trading has expanded and China is expected to comply with WTO safety expectations under a Sanitary and Phytosanitary Measures Agreement. In addition, according to a USDA Report in 2010, the Chinese government recruited growers and "supported" the growth of the juice processing industry. The Chinese export their juice concentrates worldwide and the U.S. is a big purchaser. Food and Water Watch, in a June 2011 report, stated that children eat many common foods that come from China, such as apple juice, candy, and canned fruit.

The Concerns

However, the arrival of this product is coupled with the concern of food safety. With tales of the melamine scare in the minds of U.S. consumers and articles detailing a baby formula and KFC safety scare with Chinese suppliers, red flags have gone up. In 2011, *Consumer Reports* and Dr. Oz, citing research from the University of Arizona, found that 10 percent of apple and grape juice samples had arsenic levels above FDA drinking water standards. Two years later the FDA responded with news that although testing would remain at previous levels, new guidelines would propose a level of no more than 10 parts per billion of arsenic (matching that of water)—this strengthened guidelines. The FDA website declares, "The vast majority of apple juice tested contains low levels of arsenic." It should be noted that some level of arsenic is present in soil.

Arsenic is not the only concern. An article in *The Journal of Environmental Health*, January 2012, concluded that China has poor environmental and waste management practices, excessive application of chemicals and fertilizer, counterfeit operations, lack of education regarding proper chemical application procedures, and lack of government and food safety regulations to develop and enforce food safety regulations. Additionally, an op-ed piece in *The New York Times* from August 2012 stated that China's food safety problems highlight both the collapse of the country's business ethic and the failure of government regulators to keep pace with the expanding market economy. As recently as October 2013, articles referenced a Chinese newspaper that accused three major juice manufacturers of purchasing rancid fruit. Sources indicate that this could produce a toxin, patulin, which can survive pasteurization (see "Patulin in Fresh Fruits," page 31). Finally, Edward Wong reported in the *Pittsburgh Post-Gazette* in January that fields in China are "irrigated by water tainted by industrial waste." This host of red flags does present food safety dilemmas for importers and the public as consumers.

Searching for Solutions

The U.S. has been tackling the food safety issue for some time. Hazard Analysis and Critical Control Points (HACCP) regula-

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tions have been in place for a long while. In July of 2013, the FDA announced proposed rules for the Foreign Supplier Verification Program (FSVP)—part of the Food Safety Modernization Act. According to the Act and confirmation from the Juice Products Association, juice companies are exempt from two of the seven proposed rules because of similar requirements from HACCP. Yet sources recognize that only about 2 percent of imports are actually tested.

On the flip side, the Chinese have made some inroads to ensuring food safety. Amid growing public discontent the Chinese government enacted the Food Safety Law, effective June 2009, to prohibit the use of unauthorized additives and also, more broadly, to provide a basis for strengthening oversight "from farm to fork." Health-conscious urban consumers are willing to pay a premium for safe food, according to Denise Prévost in a detailed article in *China Perspectives*, March 1, 2012. These consumer concerns prompted the government in 2010 to appoint a national commission of three vice-premiers and a dozen minister-level officials to deal with food safety. The national Ministry of Health is the lead agency for the project, which is supposed to be completed by 2015. The government has acknowledged, "Many of the regulations are overlapping and contradictory." A large number of agencies, 14, weigh in to some degree for food safety.

Early this year, the central government went a step further when they asked provincial authorities to "increase the punishment for illegal criminal behavior in food safety" (*Business Times*, January 6, 2014). Leaders plan to give food safety a high priority. At least in public messaging and enactment of laws, changes are on the horizon. How long it will take is in question. As stated by Prévost, food poisoning is still a health threat in China, somewhat based on sanitary conditions. In addition, producers, many of whom export product, have to deal with new threats of chemical fertilizers, pesticides, and genetic modification.

Reactions from U.S. Importers

What is or should be the reaction of U.S. importers? As they import juice concentrate and other products, they rely on the FDA as well as their own quality control to monitor the situation. In total, 367 million gallons of apple juice concentrate reached U.S. shores in 2012 from China. When looking at other fruits, China is documented as the leading exporter to the U.S. of prepared peaches and pears (98.6 million and 50.7 million pounds, respectively). The U.S. imported a significant amount of frozen raspberries from China as well.

Reaction to food safety concerns from U.S. companies producing and selling apple juice is mixed.

Reaction to food safety concerns from U.S. companies producing and selling apple juice is mixed. The company website for Michigan-based Old Orchard proclaims, "Apple juice concentrate has been safely imported into the U.S. from countries including China, Brazil, Argentina, and Chile for more than 10 years without incident."

Nestlé Beverage Division reports it does import apple juice concentrate from China as well as South America. "Regardless of the country of origin, all of our imported apple juice concentrate is tested in the U.S. before we use it and must meet Nestlé's strict quality guidelines—which always meet and often exceed U.S. guidelines. If it doesn't meet our guidelines, it doesn't go into our juice," says Joanne Crawford-Dunér, marketing communications.

A Washington state juice producer, Tree Top, reconsidered the purchase of foreign, including Chinese, juice concentrate. Largely the change was to appeal to what they perceived their customers desired, according to comment from the corporate communications department. "We have not imported juice (fruit) concentrates in more than two years due to the availability of U.S. processor grade fruit for making juice concentrate," states Sharon Miracle-Harris, Tree Top corporate communications director. The company decided in 2008 to only use U.S. apples "in order to meet our consumers' preferences." Miracle-Harris acknowledges that when asked to assess the capacity of China to improve safety, "Any additional federal requirements such as field auditing in foreign countries where a company may not have employees with expertise...will certainly take additional resources." She also notes that it might take a long time for the Chinese to comply.

A small producer of juice and apple cider in Minnesota, Pepin Heights, combines its own apples with 50 other Midwest growers to produce product, including cider and juice for sales to about 30 states. It too is remaining local and cognizant of consumer attitudes.

Currently, in somewhat of an ironic twist, the lure of potential markets has American apple and juice producers looking to export to China. Some of the why can be explained by comments in China Agribusiness Report, Quarter 1, 2014, published by *Business Monitor International*. The Chinese, who have increased purchasing power, are looking to value-added energy drinks and juices as they seek a healthy life. This likely will lure investments from regional and global soft drink manufacturers. (Tropicana, a juice producer, is one of them, according to the article). Other groups looking to export to China are Washington state apple growers. They actually did so until about a year ago, when the Chinese put a halt due to worries about apple disease. China did this in part to encourage its own export of Chinese apples to the U.S. Thus far, the USDA recognizes that pests (on the apples) are a problem and has not allowed this Chinese import. China has curbed imports in the past from Europe as well as the U.S. under a variety of reasons.

In conclusion, consumer demand, supply of apples and concentrate, and federal regulations all play an important part in the export-import process. The food safety issue, although not solved, remains a high priority for all participants. Will all the proclamations turn into actions? The enormity of the task for China means that waiting for real change may demand patience. In the meantime, American importers will need to be diligent as they meet the demands of consumers who are savvy and share opinions via social media. Chinese consumers, too, are becoming more aware of food safety and that likely will help propel their government to keep on top of safety regulations. ■

Fronek is a Minneapolis-based freelance writer and member of U.S. China Business Connections Group, Minnesota. Reach her at kfrons@comcast.net.

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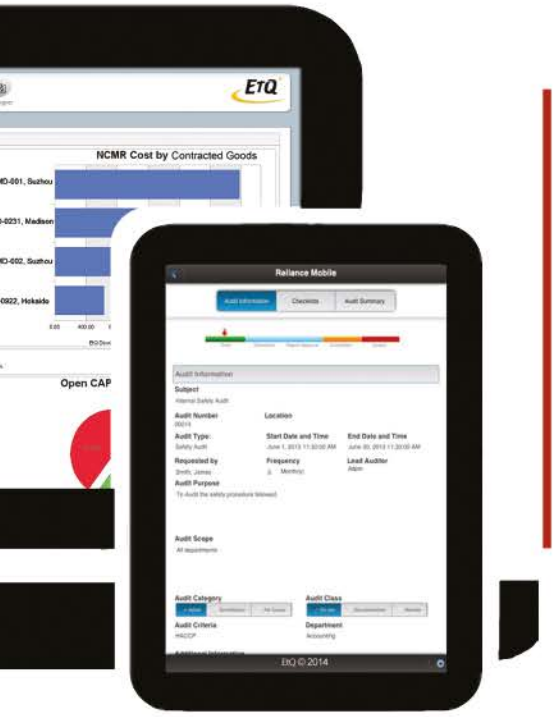

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COVER STORY:

ROUNDING UP CONTAMINATION

A key component to safeguard the animal food supply involves harnessing potential contaminants

BY **HENRY TURLINGTON, PHD**

IN ANIMAL FEED

TODAY'S CONSUMERS ARE VERY INTERESTED IN THE SAFETY of our food supply. They also show a growing concern when it comes to the food supply provided to the livestock our farmers and ranchers raise, and even more, animal food available to their pet family members in their own homes.

Over the years, several high-profile events have raised the awareness of animal food safety that spotlighted the risks to our food chain. The bovine spongiform encephalopathy outbreak in the 1990s, better known as BSE, and the melamine contamination in pet food in 2007 are two well-known and publicized past events in the industry. Although rare, these events still gain the public's attention; but in fact, many more million tons of feed is manufactured safely each year.

Last year, there was more than 150 million tons of animal feed manufactured by 6,700 feed mills in the U.S. This does not include more than 8 million tons of pet food manufactured in the U.S. These animal feeds required multiple raw materials mostly from crops grown within the U.S. or Canada.

Many of the ingredients used by the animal feed industry are materials not used for human consumption or are products remaining after processing materials for human food, known as co-products for animal feed. This includes materials such as bakery byproducts, dried distillers grains (from beverage and industrial ethanol production), soybean and cottonseed meals and hulls (from vegetable oil processing), molasses (from sugar production), and peanut skins.

In addition, most animal feeds are manufactured as complete diets for animals and fed as the sole food for animals. Thus, the type of animal and the animal's life stage impacts the nutritional fortification of the feed to ensure the animal's needs are provided.

There have been almost 500 recalls of animal foods from 2013 to the present. Of these recalls, 95 percent were pet products, primarily due to suspected *Salmonella* contamination or risk (89 percent). With the majority of pet foods fed within the home, microbial contamination is a major concern for the industry to ensure the safety of the pet owners. For livestock, such as cattle, poultry, and pigs, *Salmonella* contamination is not as worrisome of an issue, as the feeding environment and the feed processing do not pose a food safety risk for humans.

Industry is faced with a variety of potential contaminants within animal feed, mostly the contaminants come from incoming materials. It is important to assess the severity and probability of the potential contaminations in order to determine the actions required, if any, to control the potential risk. The principles of Hazard Analysis and Critical Control Points, or HACCP, program are useful in order to manage the potential risks from contamination, which can be divided into physical, chemical, and biological risks.

THE RISKS

Physical. Bulk materials are the most common source of physical contamination. Proper inspection prior to unloading is the first step in minimizing the risk of contamination. A bulk material may be transported several times (harvest, rail, truck, etc.) before reaching a feed mill for processing into animal feed. Thus, materials are screened to remove debris that does not belong in the ingredient and may have been introduced during transport. Magnets are used to remove ferrous materials throughout the manufacturing process, including during receiving. Most physical contaminants do not create food safety risks for the animal or humans.

Chemical. The highest potential risks for animal food safety come from chemical contamination. The most common risk is mycotoxins, which form naturally within grains.

Mycotoxins: Produced by fungi grown on forages and grains that are stressed during the growing season, mycotoxins may also form during storage of grains due to ideal conditions (moisture and temperature) for fungi growth. Mycotoxin action levels have been established by the U.S. FDA for aflatoxins, vomitoxins (de-

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Major Classes of Mycotoxins, Common Food Products that may be Contaminated and Animals that are Most Affected

Mycotoxin	Contaminated Products	Animals Affected	Clinical Effects
Aflatoxins	Corn, peanuts, cottonseed, tree nuts, dairy products	Swine, dogs, cats, cattle, sheep, young birds, humans	Liver damage, intestinal bleeding, cancer
Ergot alkaloids	Rye, sorghum, pasture grasses	Cattle, sheep, humans	Hallucinations, gangrene, loss of limbs, hastening of birth
Fumonisins	Corn, silage	Horses, swine, humans	Pulmonary edema, leukoencephalomalacia, esophageal cancer, neural tube defects, liver damage, reduced growth
Ochratoxins	Cereal grains, coffee, grapes	Swine, humans	Kidney and liver damage, cancer
Trichothecenes	Wheat, barley, oats, corn	Swine, dairy cattle, poultry, horses, humans	Feed refusal, diarrhea, vomiting, skin disorders, reduced growth
Zearalenone	Corn, hay	Swine, dairy cattle	Enlargement of uterus, abortion, malformation of testicles and ovaries

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oxynivalenol or DON), and fumonisins in several ingredients and finished feeds. Feed and feed ingredients above these levels can be considered hazardous and subject to recall. Other mycotoxins may be considered contaminants at levels reasonably likely to cause harm to animals or humans based on scientific research even without an FDA action level. One likely to have an established FDA action level in the future is zearalenone.

As an example, aflatoxin is a common mycotoxin found in corn. Levels greater than 20 parts per billion in a finished feed may create food safety risks for young animals. Unfortunately, FDA does not allow blending of grains to reduce the aflatoxin to an "acceptable" level, nor is there a recognized "detoxifier" by FDA for the mycotoxins. Some states allow blending of such products and a few allow ammoniation to destroy the aflatoxin, but these are for intrastate use only. Thus, the feed manufacturers must check incoming raw materials for mycotoxins to ensure the safety of its finished products. Mycotoxin testing is influenced by the type of animal being fed and the crops in which mycotoxins are most frequently associated. Most feed manufacturers also depend upon suppliers to monitor mycotoxins as a part of their supplier verification programs. Feed and feed ingredients above these levels can be considered legal adulteration. Many of the mycotoxin tests have high analytical variation, so firms should be careful in setting any "trigger" levels considerably above a FDA action level, as the tests may be as much as 50 percent below the actual level.

Medications: Medicated feeds are closely monitored by FDA through inspection of medicated feed mills. Good Manufacturing Practices are regulated through Title CFR 21 Part 225 current Good Manufacturing Practices for Medicated Feeds. Through inspections, the FDA ensures registered medicated feed mills comply with regulated requirements, which includes control of medicated additives to avoid potential cross-contamination and drug carryover into meat, milk, eggs, or fish. Medication testing plans, proper segregation and mixing procedures, records, and housekeeping are some steps manufacturers take to ensure compliance.

Pesticides: Although a potential hazard, pesticides are generally considered a low risk due to controls within industry. In 2011, FDA reported the results from a pesticide monitoring study, which

Raw Materials Used in Feeds

	2013
Corn	4,335 million bushels
Wheat	388 million bushels
Barley	59 million bushels
Oats	98 million bushels
Soybean Meal (Domestic Use)	29,031 thousand short tons
Sorghum/Milo	93 million bushels
DDGS	35.5 million metric tons
Total Forage Production	281,810 thousand tons
Alfalfa Production	57,581 thousand tons
Corn Silage Production	117,851 thousand tons
Other Hay Production	78,365 thousand tons

AFIA

Potential Contaminants in Animal Feed

Physical
- Foreign material (stalks, dirt, rocks, glass)
- Metal (equipment)
- Wood (broken pallets)

Chemical
- Mycotoxins
- Pesticides/industrial contaminants
- Heavy metals
- Medicated feed additives
- Excessive/deficient nutrients
- Dioxins/PCBs

Biological
- BSE
- Pathogenic enteric microbes

included animal feed. FDA collected and analyzed 199 domestic and 131 imported animal feed samples for pesticides. No residues were found in 134 (67.3 percent) of the domestic feed samples and in 85 (64.9 percent) of import feed samples, and unacceptable residue levels by EPA and FDA were found in only two domestic feed samples and 17 imported feed samples. Ethoxyquin and malathion were the most frequently found contaminants and together accounted for 41.2 percent of all residues detected. Dimethyl Tetrachloroterephthalate was the third most commonly detected residue (contributing 13.9 percent to the total) but was only found in import samples. Feed manufacturers tend to depend upon approved suppliers to control pesticide contamination through their own monitoring or preventive control programs.

Heavy metal: Also referred to as trace minerals, heavy metals are present in trace or ultra-trace amounts in the environment and may or may not be essential nutrients for animals. The metals can be classified into the following four major groups, based on their importance to animal health.

- Essential - copper, zinc, cobalt, chromium, manganese, selenium, iron (ferrous)—these metals are also called micronutrients and are toxic when fed in excess of the animal's requirement.
- Non-essential - barium, aluminum, lithium, and zirconium.

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- Less toxic - aluminum and tin.
- Highly toxic - arsenic, cadmium, lead, and mercury.

The highly toxic elements are frequently encountered in insecticides, fungicides, batteries, paints, gasoline additives, and phosphate fertilizers. Cadmium tends to represent the highest risk due to where contamination may occur within animal feed. Most cadmium comes from zinc smelters and from the sludge obtained from the electrolyte refining of zinc. Also, relatively large amounts of cadmium are found in commercial fertilizers containing phosphates. Levels as low as 1 parts per million cadmium may have undesirable effects. Incoming trace mineral sources containing zinc, or phosphate sources, that are susceptible to toxic heavy metals should be monitored by the supplier to ensure the potential hazard in controlled.

Animal Food Recalls 2013-14

Species	Number
Cat Food	110
Dog Food	309
Pet Food (other than Dog or Cat)	65
Livestock	11
TOTAL	495

AVMA, 2014 (www.avma.org/news/issues/recalls-alerts)

Dioxins: Polychlorinated byphenyls (PCBs) or dioxins, many considered to be carcinogens when fed for extended periods, have been identified as a potentially hazardous risk for animal feed. In 1997, FDA found contamination of animal feeds with dioxin, which resulted in elevated levels of dioxin in chickens, eggs, and catfish. The source of the dioxin contamination was traced to a mined clay product called "ball clay," which is used as an anticaking agent in soybean meal, other feed components, and complete animal feeds. As ball clay in this episode was an occasional ingredient, the industry and ball clay suppliers asked for its removal from the Association of American Feed Control Officials' *Official Publication*, thereby precluding its use again, as state law utilizes that publication as the official list of approved ingredients.

Currently, there are no regulatory tolerances or action levels for dioxins or PCBs in animal feed. PCBs have become a persistent and omnipresent contaminant in the environment. As a result, certain animal feeds, principally those of marine origin, may contain PCBs at low levels. Nonetheless, feed manufacturers work with suppliers to ensure the potential risk is controlled.

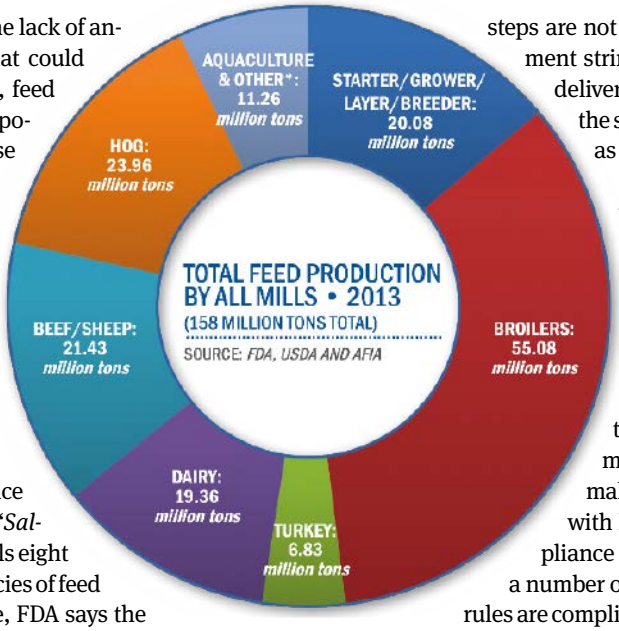
Formulation: With most animal feeds provided as a complete diet, formulation of finished products is important to ensure the proper nutritional levels are supplied for the specific type of animal and life stage. It is important deficiencies or toxicities are avoided when formulating. Review of mixing records, proper mixing times, and testing of finished product are examples of the steps feed manufacturers take to ensure finished products meet expected specifications. Proper controls of manufacturing processes ensure finished products meet the desired specifications. Feed manufacturers must identify areas that are critical processes, and establish steps that ensure the safety of finished products.

Biological. Microbiological contamination of pet food is a human food safety risk due to the pet food feeding practices and potential exposure to people. In 2012, CDC reported that a multistate outbreak of *Salmonella Infantis* infections was linked to pet food. More than 20 people across 13 states were infected. The association between human outbreaks of salmonellosis and contact with *Salmonella*-contaminated pet food and pet treats is well established. FDA launched several pet food sampling programs in the past few years, but the most recent results from 2012 to evaluate the prevalence of *Salmonella* in pet food are still pending.

Due to the potential hazards from microbiological contamination, pet food manufacturers must take steps to control the risk. This is done through manufacturing processes (segregation of manufacturing areas; stringent sanitation practices; personal flow), environmental monitoring, finished product testing (hold and release), and supplier verification programs. While such preventive controls are expensive, the potential severity and exposure of the hazard require it.

Biosecurity: For livestock feeds, microbiological contamination generally is not considered a human safety risk due to the

feeding practices of animals and the lack of animal feed exposure to humans that could create a food safety risk. However, feed manufactures must control the potential risk for the spread of disease among livestock. As an example, feed manufacturers must establish stringent biosecurity practices to prevent the spread of Porcine Epidemic Diarrhea virus (PEDv) to pigs. This includes steps during manufacturing and transport to ensure the feed or transport vehicles are not contaminated from one farm to the next.



Moreover, FDA's Compliance Policy Guide (690.800) entitled "*Salmonella* in Food for Animals" details eight serotypes of salmonellae in five species of feed that must be controlled. Otherwise, FDA says the feed may be deemed to adulterated and subject to recall if these salmonellae are discovered.

CONTROL OF CONTAMINATION

The Food Safety Modernization Act (FSMA) focuses on food and feed safety practices. The multiple proposed rules are designed to improve the safety of foods for humans and animals. Most feed manufacturers already focus on controlling contamination hazards through their own animal food safety programs. There are primarily three sources of contamination: incoming ingredients from suppliers, manufacturing processes, and delivery processes to the customer. The following steps are used to control contamination.

1. Supplier verification program. The potential for contamination is greater for incoming materials. Thus, feed manufacturers focus on controlling the risks from ingredients and their suppliers. Actions to control the potential risks from incoming ingredients may include onsite audits of the suppliers to learn more about the manufacturing processes for the ingredient and the suppliers' food safety plans; testing programs for incoming ingredients to monitor quality and food safety; requirements for certificates of analysis of shipments for particular nutrients or contaminants to ensure specifications are met; and third-party certifications by the suppliers to ensure effective food safety programs are maintained.

2. Third-party certifications. With an increasing demand for quality and food safety, many feed manufacturers obtain third-party certifications for their feed manufacturing facilities to assure customers that proper processes have been developed and implemented for food safety. Systems are available today that are benchmarked against global standards, such as the Global Food Safety Initiative (GFSI), for animal feed and pet food production. American Feed Industry Association and SQFI worked together to provide the only global standards for animal feed and pet food that are benchmarked by GFSI: FSC 34 Safe Feed/Safe Food Certification and FSC 32 Pet Food Manufacturing Facility Certification.

3. Biosecurity practices. The delivery of finished products may pose a risk for spread of animal disease if proper biosecurity steps are not taken. Feed manufacturers implement stringent biosecurity practices for the delivery of feed to swine farms to prevent the spread of disease across farms, such as PEDv.

The control of potential contaminants is a key component for a successful animal food safety plan. The feed industry has worked closely with FDA to ensure regulatory requirements are met, and the animal food supply is safe for the intended animal and the humans that handle it. As the new requirements for FSMA are defined for animal food, the feed industry will work with FDA to achieve and maintain compliance in a timely fashion. This will take a number of years, as the law and its resulting rules are complicated and demand more processes, paperwork, and patience in the ensuing decade. In the meantime, feed manufacturers will continue to strive to maintain a high-quality and safe food supply for animals. ■

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REFERENCES FURNISHED UPON REQUEST

Backyard Farms team members at Award ceremony, from left to right: Arie van der Giessen, head grower; Mark Queenan, director of quality assurance and food safety; Missy Blackwell, food safety and quality coordinator; Tim Cunniff, executive vice president of sales; and Paul Mucci, COO and president.

Attentiveness is Key to Quality Tomatoes at Backyard Farms

Winner of the latest Food Quality & Safety Award, the Maine-based grower is able to deliver fresh tomatoes all year long | BY **LORI VALIGRA**

Growing vine-ripened tomatoes in the dead of a cold, lightless Maine winter and in humid summers is no small task, nor is preventing insect infestations that can damage plants and shut down greenhouses.

But this is the world Arie van der Giessen, head grower at Backyard Farms of Madison, Maine, faces daily. He readily admits what runs his life: "The plants are the boss," he says. "They need daily attention. Day and night. The last thing I think about before bed is the plants, and they are my first thought in the morning."

Connected via a computer, van der Giessen can check statistics from sensors in the company's two greenhouses, such as temperature inside and outside and whether conditions are too wet or dry. Fertilizer, pH, calcium, growing medium, air flow between plants, signs of pests, and other aspects of the plants also are checked regularly. He walks around each greenhouse to personally look at the 420,000 plants growing at any given time with one assistant, and he hopes to hire another. "I walk 5 to 6 miles a day to check the greenhouses," he says.

It's that kind of dedication to quality by van der Giessen and Backyard's 200 other employees, combined with technology, cleaning, employee training, and other factors, that won this tomato company the 13th annual Food Quality & Safety Award (formerly the Food Quality Award). Members of Backyard's team received the Award at a ceremony on April 9 during the 2014 Food Safety Summit in Baltimore, Md. The Award, sponsored by DuPont Nutrition & Health and presented by *Food Quality & Safety* magazine, honors a North American quality assurance/quality control team that makes exceptional contributions to food safety and consumer satisfaction.

"Global food security is important to DuPont, and it is vital to recognize efforts that keep our food safe all along the food chain," says Rob McPheeters, business leader for Diagnostics, DuPont Nutrition & Health. He adds that companies such as Backyard demonstrate that their commitment to food safety not only protects the food supply, but also makes good business sense.

"We try to find the highest level certifications, like SQF 2000 [Level 3], or the latest certification. We are proactive about

Backyard Farms employee provides a final quality check for tomatoes on the vine.

BACKYARD FARMS

Preparing plants in the greenhouse that will eventually help produce an estimated 26 million pounds of Backyard Farms tomatoes over the next year.

it. A lot of the certification is customer-driven," says Tim Cunniff, executive vice president of sales at the tomato grower. Cunniff adds that while his company charges more for its vine-ripened product, customers are willing to pay for the quality. "We take more of a holistic approach to business," he says.

Mark Queenan, the company's director of quality assurance and food safety, notes that Backyard adheres to Good Agricultural Practices, Good Handling Practices, and Hazard Analysis and Risk-Based Preventive Controls. He points out that the company became the first farm in Maine to be USDA GAP Certified in 2007, and in 2010 it became the first farm in Maine and New England and one of the first in the U.S. to be SQF Level 3 certified. In 2012, it was the first farm in Maine to be GAP Harmonized certified, and it is striving to become Global GAP PSS (produce safety standard) certified in 2014. In addition, Backyard's Hazard Analysis and Critical Control Points, or HACCP, program addresses potential bacterial, chemical, or physical contaminants.

The company is also being proactive to meet forthcoming Food Safety Modernization Act (FSMA) requirements related to its business. "The biggest difference I see with FSMA is the need to address and implement preventative controls. You need to monitor and to maintain records," says Queenan. "You have to be able to show science-based methods are working."

Year-Round Freshness

Backyard started in 2004 with the realization that the tomatoes in the grocery stores were grown in Canada, Mexico, or Holland, and weren't ripened on the vine, and often not quite red in color on the store shelves. The company harvested its first hydroponic tomato crop in early 2007 from its 24-acre greenhouse in northern Maine, and added a second greenhouse in the summer of 2009 with another 18 acres of growing space. The total of 42 acres is equivalent to about 32 football fields.

Fiscal year 2013 saw its primary tomato variety improve to 6.2 kilograms per square meter (kg/m^2) from 4.7 kg/m^2 from the prior year. Its smaller tomatoes increased to 2.4 kg/m^2 from 2.3 kg/m^2, and its largest tomatoes increased to 4.4 kg/m^2 from 3.2 kg/m^2. That translates into growing more tomatoes and decreasing waste, Queenan notes.

The tomatoes are checked regularly from the time the seeds are grown at the external plant propagator through the shipment of the young plants to Backyard's greenhouses, then at the greenhouses as they grow and are harvested, and through them then being boxed and shipped.

"Once the plants are in here [the greenhouses], they are monitored continuously by the growers," adds Queenan.

Working in a hydroponic environment has its plusses and minuses. "There's a clear advantage to having a hydroponic environment that is cement and steel enclosed with potable water systems in place to closely monitor quality," he says. "We're sticklers about handwashing." The heated water system also is enclosed and can run at a consistent temperature. And there are bathrooms and plenty of sinks for employees to wash their hands, compared to an open field.

On the other hand, once the cold Maine winter sets in, the warm, moist greenhouse beckons a variety of insects, which need to be controlled. "You can't afford to have an issue," adds Cunniff. "It's devastating."

Backyard discovered that firsthand last July when a whitefly infestation forced the company to destroy all of its 420,000 tomato plants and start over, eventually not producing tomatoes for a total of six months. It cleaned out both of its greenhouses, delaying deliveries to some 30 retailers across New England, including Hannaford, Shaw's, Roche Bros., Walmart, Wilson Farm, and Whole Foods for up to 10 weeks. In August 2013, the company deemed the new starter plants for a second crop grown at its external propagator partner to be inferior, and the company sought a new supplier. Backyard had to furlough all but essential personnel until after last Labor Day and then hired them back as the business got back on its feet. After fully cleaning the greenhouses and hiring van der Giessen as head grower, it got both greenhouses up and operational by October 2013, rehired all its employees by December, and then held a "new crop" celebration on January 8 of this year.

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Cunniff remembers the ordeal as being horrible, but credits the hard work of the employees for helping the company turn around. "Going forward, one thing that is different is the level of diligence and the amount of monitoring," he says. "There's more time, more eyes, more feet on the ground. It's a different level in terms of assurances now. You can't fix what you can't see and aren't looking for. It's both systems and people." He says as a result, the company had the best January to March it's ever had in terms of tons of tomatoes shipped.

New Technology

In 2013, the company invested in new technologies to improve the safety and quality of its products, including four Amerivap Corp. steam cleaners for its food contact surfaces on its packing lines. The packing equipment is not washdown and is extremely sensitive to moisture. The company has tested combinations of sanitation technologies that are low moisture and environmentally friendly.

It also added a no-rinse vegetable wash called ProSan that works against disease-causing pathogens, spoilage organisms, and tomato plant pathogens. And it has replaced transfer belting in its packhouse 1 to improve cleaning and hygiene.

Last year it also bought two Hygiena EnSURE quality monitoring systems. The handheld units for adenosine triphosphate, or ATP, monitoring help the company prove the cleanliness of its surfaces and its validation processes within seconds, according to Queenan. The systems also can test for coliforms and *E.coli* at the beginning of a packhouse shift and reveal the results before the end of the day. Backyard also uses Hygiena's MicroSnap rapid *E.coli* protocol for detection and to keep the bio-burden low.

The company has enhanced seed, seedline, and mature tomato plant testing by hiring a plant pathologist/consultant to help it create and implement tomato pathogen protocols. It is now using RT-PCR, PCR, and Bio-PCR methods that can find minute amounts of bacteria, viruses, and viroids. Backyard also started swabbing at the plant propagator to monitor for pathogens.

Scouting

Integrated pest management (IPM) starts at the seed, according to Erika Verrier, director of IPM at Backyard. She says that early scouting for problems sets Backyard apart from many of its competitors.

"It starts at the seed. We see if the plants are up to our standard quality. And we do IPM until the plants arrive at our greenhouses," she says. "We test all the seeds and plants at the propagation facility to assure we don't invite anything into our greenhouses." Common tomato pests are the whiteflies and aphids. Plant diseases like botrytis (brown fungus) also can be a problem in a greenhouse. "If you build it, they will come," Verrier jokes.

She says a group of scouts look at every plant in the greenhouse in a two- to three-week period. "We've gotten good at managing it over the last year," she says. Every plant gets individual attention. The result: a significant decrease in botrytis in the last year. The disease had actually decreased the company's crop density 30 percent the prior year, but now the density is back to normal.

Backyard has to be particularly diligent because it uses an interplant technique, which means there is a continuous crop year round. Young plants are grown near old plants on the same gutter. Each tomato crop cycle lasts six months, with two months of overlap between the aging crop and the newly interplanted crop. "Our scouting is more intense in the two months when we have the two crops going at once," comments Verrier.

Of the current IPM team of 15 people, about half are scouts. She says the scouting part of the IPM team is unusual in the industry—the company has a designated team of full-time scouts rather than relying on consultants. "We work as a team to determine the best options for control. So we can explore other alternatives besides pesticides," she says.

One focus is on biological controls, which are working well for whiteflies—they now are at historical lows in the greenhouses. "We rear native beneficial insects on host plants in greenhouses to control whiteflies," says Verrier. In Maine, the insect is the *Dicyphus hesperus*, which acts as a biological army against whiteflies, aphids, and moth eggs. The alternative is to mechanically scrape off the whitefly or other infestations with blades. "In a greenhouse, things move quickly," she says.

One of the things Verrier says Queenan has highlighted that sets Backyard apart from other tomato greenhouses is minimizing the risk of plants not meeting the company's quality standards. And that means looking for new ways to assure quality, and to do so sustainably.

"We're currently developing a habitat landscaping project around the perimeter of the greenhouses," comments Verrier. "We want to attract beneficial insects and have an additional banking system to rear more biological controls." ■

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Food Safety Summit Recap

The 2014 Food Safety Summit, held on April 8 to 10 at the Baltimore Convention Center, provided attendees with timely workshops, pre-certification programs, informative sessions, and networking opportunities with 178 vendors on the show floor. Key members of the government were in attendance, including representatives from the Association of Food & Drug Officials, along with Town Hall participants Michael Taylor, deputy commissioner for foods, FDA, Brian Ronholm, under secretary for food safety, USDA, and Joseph Corby, executive director of the Association of Food and Drug Officials.

The Food Quality & Safety Award ceremony featured a keynote address on the food safety culture at Land O'Lakes, Inc., which was delivered by Sara Mortimore, vice president of product safety, quality assurance, and regulatory affairs. "Our goal is to have each of our 10,000 employees be quality champions, where each one knows how to do the right things—even when no one is looking," explained Mortimore.

Unfortunately, this year's Summit was overshadowed with report of an associated foodborne outbreak. At press time, the Baltimore City Health Department and Maryland Department of Health and Mental Hygiene were continuing investigation on an outbreak of gastroenteritis at the convention center. There were over 100 reported illnesses, mostly self-limited diarrhea. No related hospitalizations or deaths have been reported. *–FQ&S*

Capitalizing on Best Practices of Automated CIP Systems

Using automation to create safe, reliable, and robust CIP systems for today's demanding food production cycles

BY **STEPHEN MALYSZKO, PE**

Clean-in-place (CIP) systems are used by food manufacturers to eliminate the soil load buildup during normal production. CIP systems vary widely in configuration, operation, and the level of automation. In many companies, plant, corporate engineering, IT, and their partner integrators are pitching in to create robust automated systems to improve CIP operations by reducing cycle times as well as reducing water and chemical usage. The techies are helping production in many ways by using the most current technologies for computers, process controls, instrumentation, software, networking, and security in CIP. These platforms are being integrated into comprehensive systems to provide new levels of efficient and effective CIP operations, data capture, and real-time information analysis. Let's explore the tools making automation in CIP contribute more to the bottom line than ever before.

CIP Systems: Different But All the Same in the Eyes of Automation

Configurations vary for CIP systems. They typically include self-contained skids; kitchens with large tanks for single CIP systems; and kitchens with large alkaline, acid, sanitizer, and recovery tanks for simultaneously servicing multiple CIP systems.

Whether a CIP system is a skid or kitchen, it can consist of the following.

- One Tank – combined rinse and wash
- Two Tank – separate rinse and wash tanks
- Three Tank – rinse, wash, recovery
- Four Tank – any combination of rinse, wash, alkaline, acid, sanitizer, recovery
- In-line or in-tank chemical dosing for one-pass chemical usage systems
- Separate chemical tanks for alkaline, acid, and sanitizer for multi-pass chemical usage

Components common to the variety of CIP systems include water supply source; supply pump; supply-side heat exchanger and temperature transmitter; tank inlet, outlet, and recirculation valves; chemical addition pumps; and chart recorder, either paper-based or electronic, to record, at a minimum, temperature over time.

CIP operations can be successfully run with this configuration, although a high degree of manual control, constant monitoring, and intervention is necessary to insure effective and safe operation. Production usually finds it very difficult to maintain consistency of chemical concentrations, wash temperatures and times, and rinse water quantities. Worse yet production may routinely over compensate the operation by adding more chemicals to insure minimum cleaning requirements are met or running at higher temperatures, longer wash times, and greater rinse water quantities; all more costly to operations.

Better Instrumentation and Controls

Manufacturing can significantly increase efficiency and reduce operating costs for CIP by enhancing systems with additional components. More robust CIP systems will have the following components.

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Supply side flow transmitter – rinse and wash steps can be precisely controlled by totalizing the liquid quantities delivered to each CIP circuit.

Variable frequency drive on the supply pump – supply side flow rates can be precisely controlled with a loop control tied to the flow transmitter above. The benefits gained are ensuring line circuits achieve minimum liquid flow velocities for surface contact in the various pipe diameters, and sufficient flow through spray balls for tank circuits.

Supply side line pressure transmitter – monitor point to detect if an obstruction in the circuit is present when pressure is too high or a break in the circuit exists when pressure is too low.

Level transmitters or level probes on the tanks – used to signify when action needs to be taken; especially when low levels are reached before or during a CIP operation.

- Fresh water tanks – refill to a mid or high level
- Chemical tanks – add more water and the appropriate chemical to have sufficient solution for the appropriate wash step(s)
- On high level – stop filling the tank

pH transmitters for alkaline and acid tank makeup – monitor point used when combining water with the alkaline and acid chemicals to the desired concentrations and pH levels.

Proximity sensors – for all possible connections made at manual hook-up stations or "swing panels," monitor points; used when initiating a cleaning circuit to verify all connections are properly in place for the specific circuit; used during the cleaning sequence as a safety monitor in the event a hook-up connection comes loose potentially spraying hot water and/or dangerous chemical solutions in an area.

Return side temperature transmitter – monitor point to insure the entire circuit is being cleaned at the required minimum temperature.

Return side liquid flow switch – monitor point to detect liquid is returning to the skid or kitchen from the circuit being cleaned. Typically used in conjunction with a timer creating a notification to the operator to stop the system and check for leaks or to check for incorrect circuit hook-up points.

Return side conductivity transmitters – monitor points to detect the absence or presence of chemicals. Rinse step times can be shortened when chemicals are not detected in the liquid returning to the skid or kitchen. Conversely, wash steps can be initiated sooner when chemicals are detected at the required concentration level in the return solution. In some applications a second, more sensitive, conductivity transmitter is used to sense the complete absence of chemicals in the final rinse step.

Return side turbidity meter – monitor point to detect the amount of solids in the return liquid stream; used to prevent liquids with high solids content from being directed into a recovery tank.

Process controller, such as a PLC or DCS – used to control the CIP steps together with checking for limits and alarms. This topic is covered in more detail below.

Human-machine interface (HMI) – the operator's window into the system for control and monitoring the CIP process while operating. Again, this topic is covered in more detail below.

Performance-Packed CIP Controllers and HMI Platforms

CIP Control Platforms. A variety of PLCs and DCS platforms are well suited for controlling the range of simple to robust CIP systems. Simple CIP systems many times have a small stand-alone PLC or DCS controller. More operational complexity and additional instrumentation in the CIP system generally sets the need for more powerful controllers. Both PLC and DCS control platforms offer features attractive to users from different perspectives and preferences. The more common attributes of both platforms are ability to handle a variety of field devices found in today's manufacturing environment; ability to interface to multiple device communication networks such as EtherNet/IP, ControlNet, DeviceNet, Profibus, AS-i Bus, Foundation FieldBus; ability to create structured code along with intuitive labels and tags within the programming; and closer integration with the HMI's and data historians, event archivers, and relational databases (covered below).

Process controllers no longer live on the plant floor as separate "islands of automation." Rather process controllers closely work together. Controllers are tightly integrated for both process and CIP. For high-availability and high-criticality applications, several process controller manufacturers offer redundant "hot-backup" configurations addressing the concerns over "single-point" hardware failure.

HMI. The user interface between the operator and the CIP process, commonly referred to as the HMI continues to be the most dominant window into the CIP process. The typical traditional HMI hardware platform was a stand-alone proprietary device or a Windows-based computer tied to either a proprietary bus or an Ethernet network. The preference in hardware platforms for HMIs is rapidly changing in food manufacturing. Thin clients and terminal servers are being used in both new applications and upgrades to legacy process control systems for CIP.

Thin clients are, generally, diskless processors that interface over an Ethernet network to a server where terminal server HMI software and application files reside. Thin client hardware requires minimal configuration compared to thick clients (traditional Windows-based computers or proprietary stand-alone HMIs). Different process and CIP screens can be simultaneously viewed by operators at different HMI workstations (thin clients).

Plant operations have seen savings using terminal services and thin client technologies. Food manufacturers have seen 33 percent savings in PC costs for operator workstations; 55 percent reduction in power consumption by the operator workstations; and reduction from four hours to less than 30 minutes for a technician to replace an operator workstation.

Combining the Two for More Bang. These robust controller and HMI technologies, combined with the additional instrumentation can provide production with more efficient CIP operations. Consider the following time and money-saving enhancements.

Recipe-based CIP circuits – make CIP circuit parameters part of a selectable recipe through the HMI. The parameters can include rinse and wash times/quantities, drain times, flow rate and temperature set points per step, line pressure limits per step, conductivity and turbidity limits per step, quantities of chemical additions, and alarm limits for all operating parameters.

Systems can be configured to allow these CIP circuit recipes to be created and edited by an authorized person without the intervention of a programmer. All parameters are viewable and accessible from menu screens on the HMI. Each CIP circuit recipe is then stored in the controller.

Real-time monitoring of the entire CIP process – the operator sees an intuitive view of the progress and condition of the cleaning process. Information on the HMI includes which CIP circuit is being run, current step being run, condition to complete the step, next step to run, elapsed step time, time remaining in the step, target and current flow rate, supply pump speed reference, target and actual supply and return temperatures, conductivities, pressures, pHs, tank levels, valve positions, liquid flow path, system notifications, warnings, and alarms. The operator is constantly shown when the CIP system is operating as intended and is immediately notified when wash and rinse parameters are outside allowable limits or an abnormal operating situation occurs.

Real-time trending – the operator can view at the HMI the performance of flow rate, temperatures, pressures, conductivities, pHs, and turbidity during the CIP process.

Historians for Data and Events

CIP Process Data. Traditional methods for recording process parameters, such as CIP temperatures, to meet regulatory compliance relied on paper-based circular or strip chart recorders. Maintenance of these electro-mechanical devices was always a top priority to insure their reliability, accuracy, and repeatability. Each chart recorder had multiple points of mechanical failure including the ink dispenser, ink supply, and pen driver mechanisms.

Today, food manufacturers are eliminating chart recorders and replacing them with historians; software-based data recorders extracting CIP process parameter values on a continuous basis from the PLC or DCS controllers. Today's data historians can simultaneously and continuously record tens of thousands of individual process parameter points per second. Most data historians use data compression algorithms to optimize the use of mass storage either on a local computer or in the cloud.

Trends of the CIP parameters, such as temperatures and flows, can be displayed on the HMI as well as printed out for inclusion with paper CIP records. The raw data is electronically stored and available for review and analysis days, weeks, months, or years later.

CIP Event Archiving. Traditional methods for recording events, such as circuit start time and end time or target and actual wash times and quantities, have been paper records created by the operator. These manual records do meet regulatory compliance and are very labor intensive. Their accuracy and completeness rely entirely on the operator. Maintaining paper records becomes critical for traceability of the cleaning process.

Like the historians described above, food manufacturers are moving away from the paper-based CIP records and embracing software-based event archivers and report generators. Similar to the historians, the event archivers, or transaction managers, record events germane to the CIP process. Typical recorded events include CIP circuit start and completion times, wash times and quantities, operator interventions such as putting the system in "hold" or advancing a step, repeating a step, or aborting the circuit. The significant advantage to using software-based transaction managers in lieu of paper records is the critical event data is automatically captured via the process controllers and HMIs then stored in a relational database such as Microsoft's SQL Server. Once the event data is captured, CIP and other reports can be generated.

The event archiver and reports can also be created to be compliant with regulatory requirements for electronic records. Executing this step provides the food manufacturer the ability to eliminate paper records for CIP.

Summary

Food manufacturers can improve their CIP operations and efficiencies by effectively utilizing current technologies for CIP process automation. These technologies have already been used in applications. Critical to reaping the benefits of using these newer platforms is to have the system designers, production, maintenance, and quality work closely together from a project's inception to completion so all system requirements, specifications, documentation, and regulatory requirements are cohesive and uniform. Success is achievable for those willing to take advantage of the proven technology platforms available today. ■

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Powerful LC/MS/MS Approaches for Detection and Quantitation of Mycotoxins

Control of these potentially life-threatening fungal toxins in food and animal feed is vitally important

BY **THOMAS GLAUNER, PHD**

Mycotoxins are produced primarily by *Aspergillus*, *Penicillium*, and *Fusarium* fungi growing on a variety of agricultural commodities worldwide. They pose a major threat to human and animal health, as they have been implicated as causes of cancer and mutagenicity, as well as estrogenic, gastrointestinal, urogenital, vascular, kidney, and nervous disorders. Some may also impair resistance to infectious disease by compromising the immune system. Their impact on human health, animal productivity, and international trade results in significant economic losses.

The mycotoxins that pose the biggest threat to food safety include the aflatoxins, ochratoxin A, and toxins produced by *Fusarium* molds, including fumonisins, trichothecenes, and zearalenone. Aflatoxins (B_1, B_2, G_1, G_2, and M_1), are the most toxic, including damage to DNA that can cause cancer in animals. In fact, AFB_1 and mixtures of AFB_1, AFG_1, and AFM_1 are proven human carcinogens, and AFM_1 and AFB_2 are designated as probable human carcinogens by the International Agency for Research on Cancer (IARC). They contaminate many crops grown in hot and humid regions of the world, including peanuts, corn, cottonseed, and pistachios.

Ochratoxin A is produced by several *Penicillium* and *Aspergillus* fungal strains, and it occurs in a large variety of foods. It is classified by the IARC as a probable human carcinogen and is also implicated in kidney damage, birth defects, and immune deficiency.

Fumonisins are the result of fungal infection of maize, tomatoes, asparagus, and garlic, but maize-containing foods are the major food safety concern for fumonisin contamination. There are at least 15 related fumonisin compounds, and fumonisin B_1 can cause necrotic lesions in the cerebrum in horses, and pulmonary edema in swine. The fumonisins are weak carcinogens in rodents and probable human carcinogens that have been associated with esophageal cancer in South Africa and China. The level of fumonisin contamination in corn was relatively high in the U.S. between 1988 and 1991, but has been low in recent years.

Only a few of the nearly 200 trichothecenes occur at concentrations high enough to pose significant threats to human health. The most prevalent of these is deoxynivalenol (DON), also known as vomitoxin. DON occurs predominantly in grains such as wheat, barley, oats, rye, and maize, and it is immunotoxic in animal models. It is not a known carcinogen and its major symptom in animals is reduced feed intake. Large amounts of grain with vomitoxin would have to be consumed to pose a health risk to humans. Type A trichothecenes like T-2 toxin or HT-2 toxin are more toxic to mammals than type B trichothecenes such as DON, but fortunately often occur in lower concentrations. Oats are the most prone cereals for contamination by trichothecenes, followed by barley and maize.

Zearalenone is an estrogenic compound found almost entirely in grains that has received recent focus due to concerns that environmental estrogens can disrupt sex steroid hormone functions. In fact, occasional outbreaks of zearalenone mycotoxicosis in livestock have caused infertility. Zearalenone has also been reported to have genotoxic activity.

Regulating Levels in Food and Feed

Limiting mycotoxin exposure to humans and agricultural animals is paramount, and more than 100 countries regulate levels of mycotoxins in foods and feed because of their public health significance and commercial impact. The U.S. FDA has established advisory levels for DON and fumonisins and action levels for aflatoxin, but regulatory limits have not been established in the U.S. for mycotoxins. China, Brazil, and Mexico have the most comprehensive legislation on aflatoxin. China and Russia have established limits for ochratoxins in cereals and other products. Several countries, including India and Japan, have maximum limits for DON. However, in the international markets, no maximum limits for fuminisins exist in several countries, including Russia, Canada, and many Latin American countries. Several countries do have maximum limits for zearalenone.

The European Union (EU) has comprehensive regulations that are referenced by several other countries for establishment of their own limits. Commission Regulation (EC) No. 1881/2006 and its amendments set out specific rules in relation to mycotoxins and other contaminants. It includes specific maximum levels for 11 mycotoxins, including aflatoxins, ochratoxin A, type A and B trichothecenes, fumonisins, and zearalenone. This regulation applies to all food business operators involved, for example, in the import, production, processing, storage, distribution, and sale of food.

Efficient Testing

Most traditional methods for the determination of mycotoxins in food or feed have been single-analyte methods, and few of them used liquid chromatography

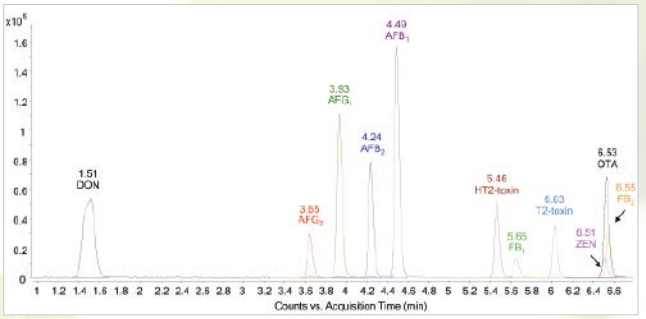

Figure 1: Chromatogram of a calibration sample containing all 11 EU regulated mycotoxins illustrating the separation efficiency of the UHPLC method run on an Agilent 1290 Infinity LC system and an Agilent 6490 Triple Quadrupole LC/MS.

coupled to tandem mass spectrometry (LC/MS/MS) until a few years ago. However, tandem mass spectrometry is a powerful tool capable of accurately detecting and quantitating the levels of mycotoxins that are dictated by the regulations. Several LC/MS/MS methods have been developed that enable high throughput analysis of food products for accurate and reproducible quantitation of very low levels of several mycotoxins at once. A few are presented here.

Accurate quantitation in complex food matrices can be hampered by suppression or enhancement of the analyte signal due to matrix effects during the mass spectrometry ionization process. Differences in the degree of matrix effects cannot only be expected between different commodities but, to a lesser extent, also between individual samples of one matrix type.

There are different strategies to compensate for matrix effects such as the dilution of the sample, matrix-matched calibrations, standard addition, or the use of internal standards. For busy routine testing laboratories, the use of internal standards which behave exactly like the target compounds but are still distinctive, is most attractive. In the past, internal standards have often been analogs of a single compound or group of compounds. However, this has limited value when the intention is to compensate for matrix effects, since such effects are retention time dependent and target compounds rarely elute concurrent with such analogs.

Stable isotopically-labeled compounds are ideally suited as internal standards since they share the same physicochemical properties (meaning they elute together with the target compound) but are still distinguishable by MS due to their different molecular mass. In addition, they are not present in naturally contaminated samples. Since the naturally abundant isotopic distribution of the analyte is diluted by the addition of stable isotopically labeled compounds, this procedure is often referred to as stable isotope dilution assay (SIDA).

A SIDA LC/MS/MS assay has been developed for the analysis of the 11 mycotoxins regulated by the EU in maize. To assure accurate quantitation, a uniformly (^{13}C)-labeled homolog for each target analyte was used as the internal standard (Figure 1). A two-step extraction without further cleanup was combined with ultra high performance liquid chromatography (UHPLC) separation and highly sensitive MS/MS detection using Dynamic Multiple Reaction Monitoring (dMRM). This method was successfully validated for maize based on method performance parameters

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including linearity of response, the limit of quantitation (LOQ) based on the signal-to-noise (S/N) ratio, and repeatability. The accuracy and reliability of the method were proven by analyzing several test materials with well-characterized concentrations. The key benefits of this method are the simple and complete extraction, the improved accuracy for a wide variety of matrices enabled by efficient compensation of all matrix effects, and high sensitivity.

Providing feed to cows that is contaminated with mycotoxins can result in the contamination of products processed from their milk, including infant formula. The EU regulation for the presence of mycotoxins in formula is quite stringent, limiting the maximum concentrations of aflatoxin M_1, aflatoxin B_1 and ochratoxin A, for example, to 0.025, 0.1, and 0.5 microgram/kilogram, respectively. Most current methods for this analysis involve labor intensive and time consuming sample purification and concentration steps required to achieve these detection levels using liquid chromatography with fluorescence detection or LC/MS.

A UHPLC/MS/MS assay for the EU regulated mycotoxins in baby formula has been developed that uses a simple extraction without a concentration step to attain the sub-part per billion detection limits required by the regulation. This method utilizes triggered MRM acquisition (tMRM) for ultimate confidence in the identification of the mycotoxins. Pre-selected MRM transitions trigger the collection of additional MS/MS transitions, each with optimized collision energy and maximized dwell time to enable the highest sensitivity. The collected ions are formulated into a spectrum, which is compared to a triggered MRM library spectrum for confirmation. This method enables the detection of the regulated mycotoxins in infant formula at levels below the maximum allowable limits, as is demonstrated by the results for aflatoxin M_1, which is typically associated with mycotoxin contamination of milk (Figure 2). In addition to the ideal sensitivity and precision of the method, its key benefit is the high confidence in the result due to the availability of high quality spectra down to very low concentration levels, which is only possible with triggered MRM.

Expanding Detection Capabilities

A method for the analysis of mycotoxins in nuts exploits the power of UHPLC and tandem mass spectrometry by enabling the detection and semi-quantitation of 191 mycotoxins and other fungal metabolites, in just two chromatographic runs per sample. UHPLC allows better separation of the analytes from the matrix, when compared to other LC/MS/MS methods, and the overall repeatability is superior to other published methods. This method features fast and easy sample preparation that includes only a single extraction step before injection of the diluted raw extract into the UHPLC/MS/MS. The multiplex analysis capability of the method enables a throughput of 25 samples per day.

This method has been utilized to survey 53 different nut samples for the presence of the 191 fungal compounds (Figure 3). The importance of using multi-mycotoxin methods was demonstrated by the detection of 40 different analytes in the nut samples. The key benefit of this method is the ability to detect mycotoxins in unlikely matrices. By applying comprehensive screening methods, the availability of occurrence data is greatly improved. In addition, this method is a good repository of MRM transitions for method extension of, for example, one of the two methods mentioned previously.

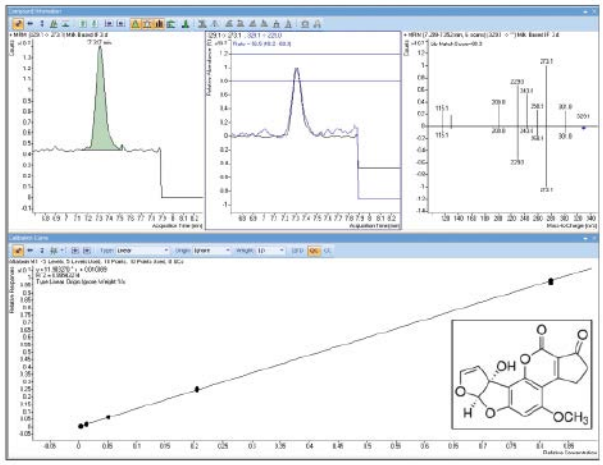

Figure 2: Extracted quantifier ion peak, qualifier to quantifier ion ratios, triggered spectra library matching (upper panel) and calibration curve and structure for aflatoxin M1 (lower panel), using the UHPLC/MS/MS method for infant formula. An Agilent 1290 Infinity LC system and Agilent 6490 Triple Quadrupole LC/MS with triggered MRM was used.

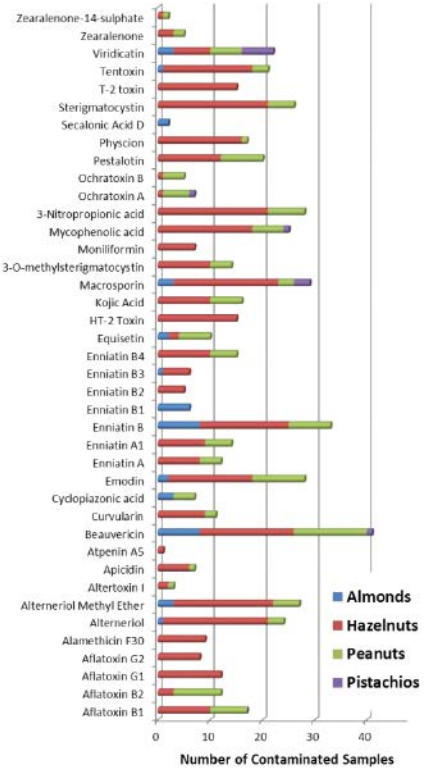

Figure 3: Forty analytes could be identified in different kinds of nut samples. The chart shows the number of each kind of nut sample that contained the given fungal compound. An Agilent 1290 Infinity LC system and Agilent 6460 Triple Quadrupole LC/MS was used.

Although aflatoxins are the only mycotoxins regulated in nuts in the EU, these results suggested that other toxins may also be relevant. Major mycotoxins found in more than 50 percent of the samples were beauvericin, enniatin B, macrosporin, 3-nitropropionic acid, emodin, and alternariol methyl ether. These results also confirmed for the first time the presence of HT-2 and T-2 toxins in hazelnuts. Analysis of such a large number of fungal toxins might be useful in the future since possible toxic effects on humans are still not fully evaluated and additive or synergistic effects of such toxins are largely unknown. ■

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Patulin in Fresh Fruits

The spoilage-causing mycotoxin presents its own unique challenges when it comes to detection procedures | BY **CHRISTY SWOBODA**

Patulin, a natural food contaminant most often associated with fruits and fruit-based products, is a mycotoxin metabolite that obtained its name from the mold *Penicillium patulinum*. As a mutagenic, genotoxic, immunotoxic, and neurotoxic, patulin can be responsible for acute effects including nausea, vomiting, and other gastrointestinal issues. It can affect a developing fetus, the immune system, the nervous system, the gastrointestinal tract, and can potentially cause DNA damage.

It's produced by several different fungi, but primarily from *Penicillium* species. Patulin has been detected in apples, pears, bananas, peaches, pineapple, blueberries, apricot, cherries, and grapes infected with *Penicillium* species. It has been associated recently with vegetables, cereal grains, and silage as it spoils. In a Food Standards Agency study which ran from 1998 to 2001, orchards were tested for the presence of *Penicillium expansum*. This fungi was found within the orchards in the soil, leaves, bark, fruit, and other orchard debris.

Patulin is associated with fruit, especially apples, exhibiting brown rot or other spoilage characteristics. Invading the fruit through insect damage, bruises, cracks, or other open spots, it can also affect varieties of fruit that exhibit an open calyx. It can be associated with poor storage resulting in spoilage of the fruit post-harvest, but prior to processing. There is an increased risk of toxin formation from long-term storage of raw fruits after harvest at ambient temperatures. Proper and safe harvesting of the fruit is critical to minimizing the risks for patulin formation. Steps to minimize damage to the fruit during harvest should occur. These

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steps can include the cleaning of harvesting bins prior to use on new crop, supervision to reduce bruising of the crop during harvest, and reduction of exposure of harvested fruit to adverse external environmental conditions. It is important to move harvested fruit to refrigerated storage within 18 hours of harvest—fruit that is left at ambient temperature for over a week to a few months shows a great increase in the risk of patulin formation from the field heat on those fruits.

Most often associated with apples, apple products, and apple juices within the U.S., the FDA believes that producers can control patulin by removing spoiled, bruised, moldy, and visibly rotting fruit prior to production as these fruits have an increased risk of toxin formation.

Patulin is very stable in fruit juices because the presence of sucrose within the juice actually protects patulin from degradation during heat treatments. A high risk of toxin formation is associated with fresh pressed juices or ciders made from spoiled or low quality fruits. Conversely, patulin contamination is often not associated with vinegars or alcoholic beverages due to interaction of the mycotoxin and yeasts during the fermentation process.

Detection

Testing for the presence of patulin in food products is not a simple or quick procedure. Current rapid test kits to detect the presence of patulin are lacking throughout the global market. The molecule of patulin is small in size and this has proven difficult for many antibody production companies to accommodate. In theory, it should be possible to produce such an antibody that could lead to a lateral flow device testing platform for a quick test of patulin presence in the production environment. Most patulin testing occurs via the use of HPLC (high performance liquid chromatography)-UV and/or liquid chromatography coupled to tandem mass spectrometry (LC/MS/MS) analyses within a laboratory. Patulin does not employ fluorescent properties and thus the use of UV detection is required. Often times the chromatography for patulin analysis is complex. A compound known as HMF (5-hydroxymethylfurfural) often times co-elutes or presents close in retention time to the patulin peak of interest. Testing methods via HPLC-UV should include a HMF standard to confirm retention time and proper separation of this compound peak from the patulin peak for quantitation purposes to avoid the potential for false positives or elevated positive results.

As the popularity of LC/MS/MS methods for detection of mycotoxins continues to rise, more laboratories are turning to this technology to accurately detect patulin contamination at low levels of parts per billion (ppb). Couple this LC/MS/MS technology with the use of a C-13 Isotope Labeled Internal Standard for patulin and the method has great sensitivity and accuracy in even complex matrices. The proper use of the C13 Internal Standard allows the LC-MS/MS system to be equilibrated to matrix enhancements and matrix suppressions for accurate quantitation. Many laboratory methods can detect patulin contamination with limits of detection at 2 ppb.

> Patulin is associated with fruit, especially apples, exhibiting brown rot or other spoilage characteristics.

Regulatory limits for the presence of patulin in food have been established in the European Union (EU) and China. To date official regulatory limits are not in place within the U.S.; however, recommendations or guidelines have been established for patulin inclusions within foods. For the U.S., these guidelines have been set at 50 microgram per kilogram (ug/kg) of patulin in apple juice, apple juice concentrates based upon single strength inclusion, and apple juice products. The guideline of 50 ug/kg by the FDA allows for a negligible risk of adverse health effects from the consumption of patulin within apple juice products over a routine period of time. China has established regulatory limits of 50 ug/kg in apple and hawthorn products. The EU has established regulatory limits of 10 ug/kg in apple juice and solid apple products for infants and young children, 25 ug/kg in solid apple products, such as apple puree, intended for direct consumption, and 50 ug/ kg in fruit juices and in drinks containing apple juice or derived from apples.

Sampling Issues

Proper sampling techniques must be employed in order to test for and detect the accurate presence of patulin within any raw fruit product or finished fruit puree, sauce, or juice. Based upon a study conducted by T.B. Whitaker and J.W. Dickens (1974), 98 percent of analytical error comes from improper sampling of the product being tested. Eighty-eight percent is attributed to sampling errors and 10 percent is attributed to sub-sampling errors from that initial sampling lot. Mycotoxins have a distribution problem within food and feeds—they are not evenly distributed across the lot of food being tested such as in proteins. Mycotoxins can exhibit clustering across the lot that can lead to either elevated or false positives above threshold or false negatives.

For proper sampling to occur, proper equipment must be utilized that pulls samples randomly from numerous spots across the lot. For raw fruits, this would include multiple samples from different bins or different locations of the bin. For purees, sauces, or juices, this would include multiple samples from different time points of the production process in order to capture a beginning, middle, and end sample at a minimum. The sampling plan should be an established protocol that is utilized in an identical pattern every time collection of a sample is to occur. By performing sampling in a routine and throughout random process, the confidence in an analytical result can be greatly improved.

The ultimate goal in sampling and analytical testing is to determine the accurate result. Ideally no patulin contamination will be detected within the fruit crops; however, should an occurrence of patulin be detected, it is critical for the sampling plan and analytical methodology employed to be sound and robust such that an accurate result is obtained for all involved parties. ■

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REFERENCES FURNISHED UPON REQUEST

Quality

ALLERGENS

New Allergen Labeling Coming to the EU

A look into what the EU Food Information for Consumers Regulation means for food manufacturers | BY **SIMON FLANAGAN**

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The new European Union (EU) Food Information for Consumers Regulation (FIC) means a significant overhaul for food processors in how they approach allergen labeling. As of December 13 of this year, all food packaging must comply with FIC and its enactment in the U.K. statute books as the Food Information Regulations (FIR). It is therefore crucial for all those working in the food industry to understand what is expected from labeling going forward, the rationale behind the changes, and how they can follow best practice both to comply with legislation and to provide the best experience for consumers. FIC has a broad remit covering nutritional information, origin labeling, and more, but here we will concentrate on the implications of the regulation for allergen labeling.

The Ingredients List

The new Regulation mandates the loss of two key familiar labeling features, meaning that manufacturers and consumers alike need to relearn how to construct and interpret allergen warnings. Perhaps the most striking instance of this is new constraints on the allergen advice boxes often used on products manufactured for the U.K. market. This is currently where allergen information tends to be concentrated; however, in order to comply with FIC these warning boxes will be severely limited in what they can state. From December onwards the boxes must not duplicate information about allergenic ingredients, but simply refer consumers to the product's ingredients list.

Only in the case where there is no legal requirement to list ingredients on the food packaging may allergenic ingredients be listed separately—wine, for example. Products such as milk, cheese, and yogurt, which also legally require no ingredients list, will not be required to be labeled "contains milk" as this is deemed to be commonly understood. In all other cases, however, allergens should be emphasized within the existing ingredients list, in **bold** type, or by other indications in the font, style, or background color.

Another aspect of this regulation to aid consumer understanding relates to suffixing allergenic ingredients with the actual name of the allergen in the ingredients lists, e.g. anchovy (**fish**) unless the name of the allergen is included in the name of the ingredient, e.g. skim **milk** powder. The allergens covered by FIC for mandatory labeling are the same as those currently included in existing labeling regulations (2000/13 EC annex iiia); cereals containing gluten, crustaceans, egg, fish, peanuts, milk, tree nuts, soy, sesame, celery, mustard and sulfhur dioxide, and sulfites (greater than 10 parts per million in finished product).

Whilst this is a significant change, and there is a clear necessity for consumer education about understanding how the new allergen information will be provided, it is hoped that once food manufacturers are all compliant with FIC that the standardization of approach will lead to far better consumer awareness. It is also worth noting that allergen information boxes are not commonly used currently in all countries of the EU, so another benefit of labeling in accordance with FIC is that consumers can be assured that they need to follow the same procedure in checking labels for allergens wherever they travel within the EU.

The other clear benefit of the new Regulation—for both manufacturers and consumers—is that there is a far reduced scope for conflicting information in the ingredients list and allergy advice box on the same product. This has in the past led to consumer confusion and potential danger to those with food allergy, and has commonly been the cause of food product recalls. Because consumers are accustomed to looking for allergen information in a separate box, they may not have checked the ingredients list, which means if an allergen has been missed from the box, the product may well be recalled for safety,

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even if the allergen is noted within the ingredients. Under FIC, however, the box may only direct customers to the ingredient list. This means that the ingredients list is the only section of the label where they can find allergen information, and thus as long as this information is correct and comprehensive there is potential for a reduced number of recalls due to label errors.

In the interests of ensuring that important allergen information is clear and legible for consumers, FIC also specifies a minimum font size for the text of allergen names in ingredients lists. Manufacturers will be required to ensure that the "x-height"—literally the height of an "x" character and its equivalents—is at least 1.2 millimeters (mm). For smaller products (where the packaging or container's largest surface is less than 80 centimeter^2), the x-height may be reduced to 0.9 mm.

All Stages of Food Chain

An additional big change for food business operators is that all the specific regulations stipulated above no longer solely apply to pre-packaged foods but also to all businesses providing foods at all stages of the food chain—food intended for the final consumer, foods delivered by mass caterers, foods intended for supply to mass caterers, catering services provided by transport leaving from the EU Member States (e.g. airline catering), and distance selling (i.e. Internet).

For foods sold non-pre-packed, such as through a restaurant or café, there is some flexibility about how the information is delivered—it could be orally, for example—but it must be made clear to consumers both that the information is available (and available pre-purchase in the case of distance-selling), and how they can obtain it. Whether this is through notes on menus, signs in restaurants, or through other means is up to the individual businesses, but they must demonstrate they have a policy in place complying with FIC and it's verifiable on challenge.

An important nuance for food manufacturers to note is that the guidance above refers only to allergenic ingredients deliberately included in the food product, as opposed to allergens that may have been accidentally introduced through cross-contamination. Information about the latter may be provided by manufacturers on a voluntary basis according to FIC. The regulation does have specific provisions however to enable individual member states to agree on common phraseology for voluntary advisory statements such as "may contain" or "not suitable for." There is also a provision to adopt action levels for advisory labeling when these are agreed by member states.

What About Gluten?

Another major change to familiar labeling conventions that manufacturers must adopt regards how cereals containing gluten are labeled. Gluten, a protein found in wheat and other cereal grains, is one of the 14 allergens that are subject to mandatory labeling requirements. Rather than just labeling "gluten" in the ingredients list, the new regulation requires that the name of the cereal is listed and highlighted in the ingredients, i.e. **wheat** gluten or **barley** flour. It is particularly important that this labeling is clear and accurate, as it may be consulted by consumers with a range of different dietary requirements: wheat allergy, celiac disease, or allergies or intolerances to one or more individual cereals such as rye or barley.

The results of implementing FIC should be positive for the industry as well as consumers: A standardized system to be followed across all product categories, potentially fewer product recalls, and less confusion across the board about what products are suitable for allergic consumers are all advantages for the food industry. However, it is crucial for manufacturers to ensure that they are in compliance with the new Regulation before December, both to avoid the legal consequences of noncompliance, and in order to reap the benefits of harmonization of labeling practices. The more knowledge that food industry professionals have about the new guidelines and the principles underlying their introduction, the smoother will be the transition into new FIC-compliant allergen labeling. ■

Flanagan is a senior consultant, food safety and allergens at RSSL. Reach him at enquiries@rssl.com.

Quantification of Natural Sugars in Baby Food

Data demonstrates that FTIR spectroscopy can provide an efficient means of sugar analysis for QA/QC application | BY **R.I. CLIFFORD, JEFF HEAD, MS, JOHN KINYANJUI, PHD,** AND **MARK TALBOTT, PHD**

No other food products focus consumer attention as those that are prepared for consumption by children. Of current interest are the natural and added sugar contents of processed baby foods and juices.

Identification and quantification of natural sugars was recently investigated in baby food products by mid-IR Fourier transform infrared (FTIR) spectroscopy. Using horizontal attenuated total reflectance (HATR), neat baby food samples were analyzed without need for extensive sample preparation. By use of the HATR technique it was demonstrated that high sensitivity could be easily achieved without significant effect from water content. Factor space chemometric analysis was used to establish a robust method that allowed the confident measurement of sugar concentrations in these food products.

The method was developed using a training matrix of three naturally occurring sugars, fructose, glucose, and sucrose. It was confirmed using a verification matrix and was found to be readily applicable to the evaluation of sugar quantities occurring in commercial baby food products. Several commercial products were analyzed with this method and quantities of fructose, glucose, and sucrose were determined.

FTIR Analysis

Baby food samples pose a unique challenge for FTIR analysis because of the strong IR absorption by water. Figure 1 shows the FTIR absorption spectra of water (red) and a 5 percent aqueous glucose solution (black) acquired using a HATR accessory with a trough liquid plate. The strong absorption bands due to water can be seen between 3,800 to 2,800, 1,700 to 1,550, and below 900 centimeter (cm)$^{-1}$. However, absorption from the glucose can be seen in the fingerprint region between 1,486 and 963 cm^{-1}. This water-free absorption region suggests that quantitative sugar analysis in aqueous solutions may be feasible.

FTIR spectra of aqueous solutions of 5 percent fructose (blue), 5 percent glucose (green), and 5 percent sucrose (black) are shown in Figure 2. The sugars have characteristic absorption bands that appear in the 1,486 to 963 cm^{-1} range. The absorption bands overlap making quantitation by least squares or traditional multivariate analysis routines difficult.

Factor Space

Chemometric factor-space analysis was utilized to establish simultaneous calibration curves for the three-sugar aqueous mixtures. Partial least squares (PLS) was selected as the factor-space routine of choice. The use of a factor-space analysis routine increased the number of dimensions in the analysis. This allowed for each sugar component to be assigned to a specific dimension or factor-space. In addition, noise in the spectra (e.g. water absorption) was also treated by the additional dimensions. By using

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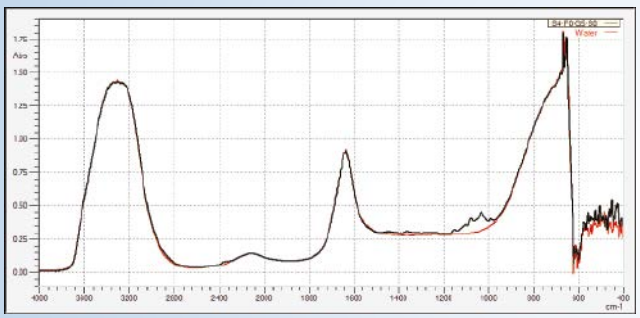

Figure 1: FTIR spectra for water and a 5% aqueous glucose.

Figure 2: FTIR spectra of 5% aqueous solutions of water (red), fructose (blue), glucose (green), and sucrose (black).

(Continued from p. 35)

the factor-based routines, the components that attributed to analytical noise (e.g. water absorptions) could readily be identified and separated out in the quantitation.

A training set of samples was prepared to cover the full three-dimensional quantitative space required for analysis of the baby foods. Since there were three sugar components of interest, fructose, glucose, and sucrose, a three-dimensional training matrix was created (Figure 3). Aqueous sugar samples were prepared to cover the eight corners of the matrix, the face centered positions of the matrix, and the matrix center.

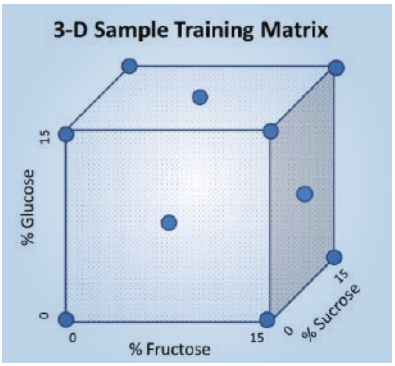

Figure 3: Three-dimensional cube showing placement of training matrix calibration samples.

Sugar Concentration (Mass Percent)			
Sample	Fructose	Glucose	Sucrose
35	1.39	12.90	0.70
36	9.58	13.77	1.16
37	2.33	13.55	14.71
38	12.92	3.95	2.58
39	6.86	10.63	9.23
40	9.90	10.82	9.89

Figure 4: Verification matrix of random aqueous sugar standards.

In addition to the training matrix, a verification matrix (Figure 4) of aqueous sugar samples was prepared using random concentrations of each of the three sugars, fructose, glucose, and sucrose. The verification matrix was used to evaluate the validity of the calibration method.

Calibration Results

FTIR Absorbance spectra were acquired of the training matrix standard samples using parameters of 4 cm^{-1} resolution, Happ-Genzel apodization, and the averaging of 32 scans. Figure 5 shows the spectra and demonstrates the complexity of the overlapping absorption bands.

A PLS algorithm was utilized to establish a calibration curve for each of the three sugar components. It was found that good correlation could be achieved without the use of pre-processing methods such as smoothing, derivatives, or zero corrections. In addition, the use of five factors accounted for all of the noise in the spectra and provided good calibration curves with acceptable R^2 values.

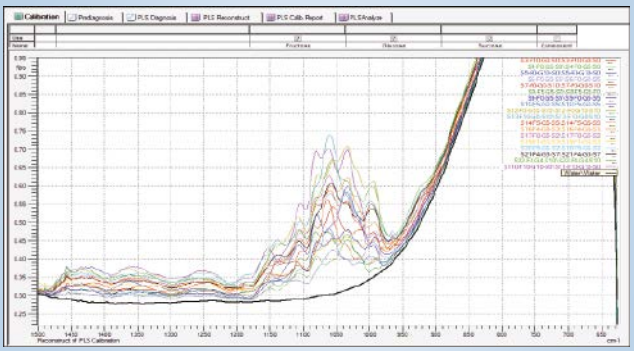

Figure 5: FTIR spectra of training matrix aqueous sugar standards.

Figure 6: P Loading graphs for each sugar supporting the selection of five factors.

To further demonstrate that the use of five factors was appropriate, the P Loadings for each sugar component were examined. As seen from the graphs (Figure 6, page 36), the P Loading of the fifth factor resembles a random noise spectrum, suggesting that all of the spectral noise had been accounted for.

Calibration Validation

Once the calibration curve for each sugar component were established, FTIR spectra were acquired of the verification matrix of samples using the same acquisition parameters as was used for the training matrix.

Results of the verification matrix showed average residuals for each sugar of 0.004 percent and established that the calibration method was valid.

> Measured total sugar values showed a high bias when compared to the reported total sugar values for all samples.

Sugar Component Analysis of Baby Foods

Commercial baby food samples from three major manufactures were acquired for fructose, glucose, and sucrose analysis. The baby foods selected consisted of pureed fruits and vegetables and fruit juices.

FTIR spectra for each baby food were acquired neat without any pretreatment using the HATR accessory and the spectral acquisition parameters noted previously. The fructose, glucose, and sucrose sugar contents were calculated using the calibration established for each sugar from the factor-spaced analysis.

Examination of the calculated residuals from the calibration suggested very good fits with the various sugar calibration curves. Baby foods that were more fruit based appeared to give better residual values, whereas baby foods that were more vegetable based generally gave higher residuals.

A total sugar concentration for each baby food was calculated from the sugar content provided on the nutrition label of each package. The calculated total sugar value from the nutritional label was compared to the total sugar value calculated from the FTIR quantitative spectral analysis. Measured total sugar values showed a high bias when compared to the reported total sugar values for all samples (Figure 7, page 38).

Conclusion

Commercial baby food samples were analyzed for fructose, glucose, and sucrose sugar content. Residual data from the calibration suggested that the baby food samples were within the calibration algorithm's area of analysis. A comparison was made of the total sugars measured to

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Baby Food Analyzed	Measured % Fructose	Measured % Glucose	Measured % Sucrose	Total Measured Sugars (%)	Reported Total Sugar Conc. (%)
Corn and butternut squash sauce	-3.25	10.55	4.52	11.82	2.65
Organic fruit yogurt smoothie puree	8,80	4.43	0.93	14.15	10.00
Peach oatmeal banana sauce	3.51	5.08	2.31	10.90	4.42
Apple sauce	7.01	2.79	1.45	11.24	9.73
Greenbeans sauce	0.68	2.34	0.36	3.37	2.65
Banana peach mango puree	5.59	5.78	5.32	16.69	9.17
Rasberry puree	7.12	4.29	0.66	12.06	9.17
Apple butternut squash puree	7.08	3.11	1.45	11.64	7.50
Banana peach coconut prune	6.90	7.61	3.38	17.88	10.00
Green pea pear puree	7.14	3.16	1.17	11.47	7.50
Apple juice	6.59	3.54	1.42	11.55	11.02

Figure 7: Total measured sugar comparison to that listed on the nutritional labels for each commercial baby food sample.

those reported on the nutritional labels of the baby food packages.

FTIR Analysis, using a horizontal attenuated total reflection accessory, was demonstrated to be a suitable method to acquire FTIR spectra of commercial baby foods without sample pretreatment or concern for IR water absorption.

Chemometric PLS routines were used to establish and validate calibration curves for fructose, glucose, and sucrose concentrations in aqueous solutions.

This data demonstrates that FTIR analysis of baby foods can offer a quick and efficient means of sugar analysis for QA/QC applications. ■

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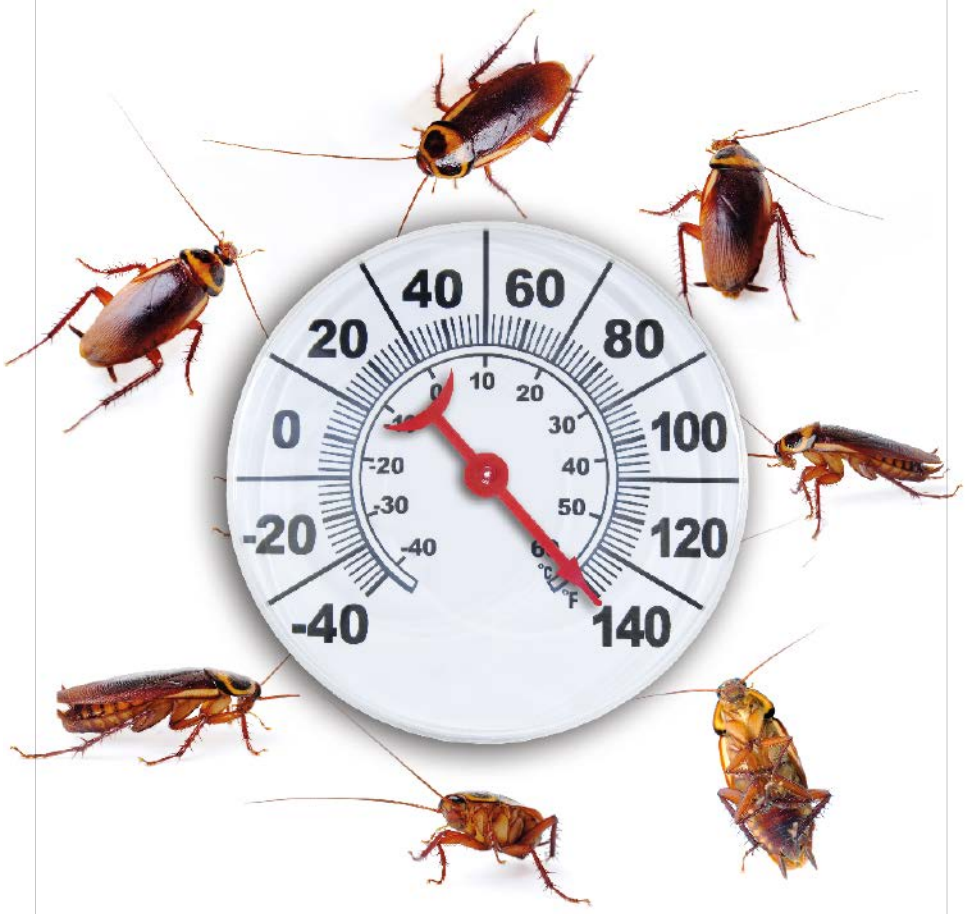
REFERENCES FURNISHED UPON REQUEST



Turning Up the Heat on Insects

An alternative to harmful chemicals, heat treatment through the use of wireless technology can manage insect pests in manufacturing facilities | BY **MARK SCHMID**

When the Montreal Protocol and U.S. Clean Air Act declared the fumigant, methyl bromide, an ozone-depleting chemical and phased out its use in 2005, food processing facilities were challenged to develop new solutions for managing insect pests.

Registered for food processing facilities, cylinderized phosphine is an option. However, it tends to corrode metals—especially at high humidity levels—and therefore is not commonly used. Sulfuryl fluoride, a non-ozone depleting fumigant, previously used for termite management, quickly became an alternative to fumigate food processing facilities. Sulfuryl fluoride dosages needed are three times that of methyl bromide, and at temperatures below 81 degrees Fahrenheit, it is less effective against the eggs of stored-product insects.

To discover safe, effective alternatives to manage the insect populations, entomologists and practitioners looked to heat. Thermal remediation, often referred to as heat treatment, is a method of heating a mill between 122 and 140 degrees Fahrenheit to strategically eliminate insects.

Heat Treatment

Bhadriraju Subramanyam, PhD, professor at Kansas State University, studies heat treatment and other tactics for managing insect pests in grain, food, and feed manufacturing facilities. His research shows that heating food processing facilities between 122 and 140 degrees Fahrenheit will kill insects at all life stages, without introducing harmful chemicals. The treatment must be maintained over a period of 24 hours so the heat can penetrate cracks, crevices, and equipment, ensuring there is no place for the insects to seek refuge from the heat. In addition, facilities must undergo thorough sanitation prior to heat treatment.

According to Dr. Subramanyam, the optimum temperature for maximum insect survival, development, and reproduction is between 82 and 90 degrees Fahrenheit. Lower and upper temperature limits, in general, for stored-product insect existence are between 55 and 105 degrees Fahrenheit. Temperatures 122 degrees Fahrenheit or above can disrupt the ionic balances across cell membranes, injure cellular DNA, dehydrate insects, destroy protein synthesis machinery, or denature enzymes—all of which can cause insect death. Depending on the insect species and the life stage exposed, death occurs within minutes to hours at these high temperatures.

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While high temperatures are an important factor, maintaining the temperature for a sufficient time is also critical because heat needs to encompass all parts of the facility. For example, insects may try to "hide" within equipment or hidden spaces to escape the heat treatment. To eliminate this risk, it is important to thoroughly clean the facility and equipment, and maintain high temperatures (target 135 degree Fahrenheit) for at least 24 hours. According to Dr. Subramanyam's research, a typical heat treatment from setup to cool down lasts about 30 to 48 hours. Insects may also seek refuge in product spillage. Removing any food products and packaging materials is critical to mitigating this risk.

Insects may try to "hide" within equipment or hidden spaces to escape the heat treatment.

Risks of Heat Treatment

While heat treatment is an optimal solution for managing pests, it can present risks to the facility if the temperatures are not properly controlled. Excessive, prolonged heat can potentially damage the mechanical structure in facilities, or even its electrical components. Since materials expand and contract at different rates, mechanical components or even the building structure can be compromised if temperature is elevated too quickly. Furthermore, electrical components exposed to excessive heat outside of their recommended operating temperature can fail. The rate of heating should be slow and a temperature of 122 degrees Fahrenheit should be attained in about 10 to 12 hours. Temperatures should not exceed 140 degrees Fahrenheit.

In addition to costly repair and replacements, damaged mechanical structures and equipment can have a significant impact on production—causing downtime.

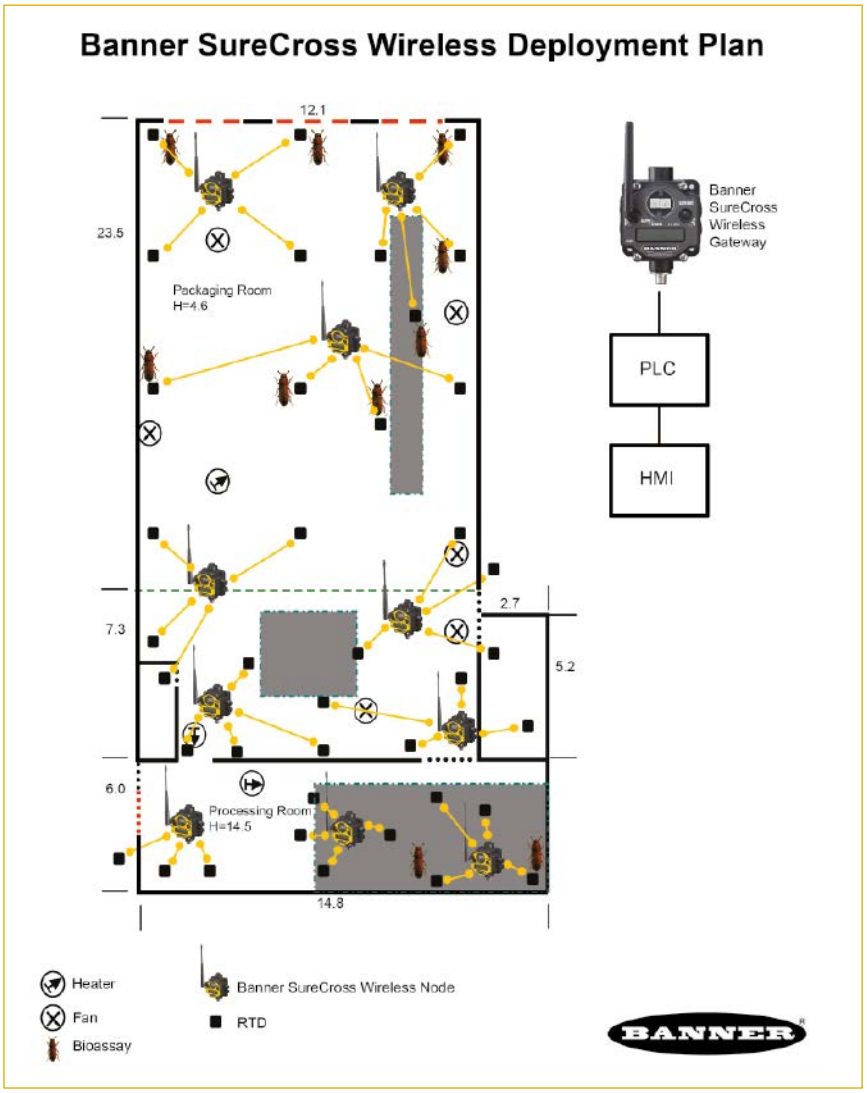
As the heat treatment is progressing, check temperatures in locations where you suspect insects are commonly found to ensure temperatures are above 122 degrees Fahrenheit. If temperatures are below 122 degrees Fahrenheit, insects will survive; therefore, move fans to eliminate "cool spots" or place additional heat sources in the area. Properly monitoring temperatures will ensure optimum results. Dr. Subramanyam's research in commercial facilities has shown that the speed of insect death was positively related to how quickly temperatures reached 122 degrees Fahrenheit, and negatively related to how long temperatures were held between 122 and 140 degrees Fahrenheit.

Monitoring Temperature During Heat Treatment

Accurate and consistent temperature monitoring during heat treatment processes is crucial to protect valuable mechanical devices and facility structures; protect electrical components; and ensure all areas of the facility have reached and sustained effective temperatures to minimize the possibility of pests repopulating.

Since most food processing facilities weren't built to accommodate heat treatment monitoring, facility managers are required to retrofit temperature monitoring tools and equipment—often having to run lengthy amounts of cable before each scheduled heat treatment.

A seven-story flour supply mill in the Midwest installed resistance temperature detectors (RTDs) throughout their mill to help monitor the facility during heat treatments. Prior to each heat treat, cabling was run to the RTDs. Some points were easy to access with cabling, while others were more remote. Since flour mills have multiple stories, the process was labor intensive and time consuming.



Banner's DX80 gateway connects up to 47 nodes—and each node can be connected to up to four RTDs.

BHADRIRAJU SUBRAMANYAM, PHD

The mill eventually installed a wireless network to access temperature information throughout the facility without running cables to the RTDs. Wireless nodes were wired to the RTDs and mounted remotely throughout the facility. The RTDs

While high temperatures are an important factor, maintaining the temperature for a sufficient time is also critical because heat needs to encompass all parts of the facility.

signal is communicated through the node and transmitted wirelessly to a remote gateway. The gateway was able to communicate temperature data to the centralized control, which would log the data and post results on an HMI.

By using wireless technology, grain mill operators can reliably monitor any remote area while communicating temperature status.

Radio and I/O terminals contained within a single housing unit rated IP67—reduces the need for additional enclosures. With this setup, users have the flexibility to install, uninstall, and reinstall in a new location as heat treating cycles are complete.

To ensure scalable coverage, it's important that wireless systems enable users to connect multiple nodes to one gateway. For example, Banner Engineering's DX80 gateway connects up to 47 nodes—and each node can be connected to up to four RTDs.

To enable operators to communicate through steel and concrete, operators should select a 900 mhz radio because it has better penetration than 2.4 ghz radios through concrete floors and walls. Banner radios come in frequencies of 2.4 ghz or 900 mhz and up to 1 watt of power. The 900mhz radios tend to do a better job of penetrating steel walls and concrete and are often used in buildings. It is important to note that while this bandwidth is available for use in the U.S. many other countries don't allow it. Banner also provides radios with site survey mode to allow users to send test packets of data across the network to confirm radio communication. The radios then report how many data packets were received.

Conclusion

Heat treatment is an EPA-compliant alternative to methyl bromide for managing insect pests in food and beverage facilities. Achieving and maintaining appropriate temperatures is important during heat treatment to ensure all insects are killed–and to protect the structural integrity of the grain mill and its components. Wireless technology provides an efficient and reliable solution to accurately monitor and control temperatures. ■

Schmid is the business development manager, food and beverage, at Banner Engineering. Reach him at mschmid@bannerengineering.com.

Special Report

Improving Auditor Competency

Recent auditor survey helped verify gap analysis of food safety auditor/inspector training needs in the development of new curriculum

BY **GARY COLEMAN, REHS, MS, MSEH, CP-FS, DAAS, ASQ-CHA**

UL EduNeering, a developer and supplier of online training is developing a food safety auditor and inspector training curriculum that supports the new National Environmental Health Association (NEHA) Food Safety Auditor (FSA) credential. The training program is scheduled for a final pilot session during July 2014 and will be publicly released within 60 days following the pilot. This program incorporates principles of adult learning and is felt to be a credible product that supports the intent espoused by U.S. FDA for a fully integrated food safety system (IFSS) and is built in collaboration with the food industry.

The need for an IFSS is based upon the prevalence of foodborne illness outbreaks and food product recalls that continue to occur in a country with one of the most sophisticated and successful food safety systems in the world. In 2013, the CDC estimated the occurrence of the foodborne illness in the U.S. alone to be over 48 million cases, of which over 3,000 deaths resulted. Additionally, vast economic losses from lost wages, legal battles, loss of sales, and business reputation are also associated with almost daily food product recalls, many of which are not associated with actual foodborne illness cases, but from suspected adulteration, inadvertent contamination, lack of allergen declarations, or other labeling problems, lost wages, and legal battles, for example.

Foods regulated by FDA are inspected by its staff and by contract with state, local, and territorial officials, regardless of whether those foods are produced in the U.S. or imported. Those same foods are the subject of many food safety audits by industry, including scrutiny by first-, second-, and third-party auditors.

Realization of the vast magnitude of food products with differing and unique hazards associated the difference in competencies of the inspectors and auditors, and the differences between an inspection and an audit scope, the importance of ensuring the competency of inspectors and auditors alike is vital.

To that end, FDA, under the "Integrated Food Safety System's National Food/Feed Training Program" provided funding to support a uniform and comprehensive food safety system intended to include inspections, laboratory testing, and response while prioritizing "prevention" as the first line of defense against foodborne illness.

Planning an Audit: how important are these topics?

Answer Options	Important to Extremely Important	Slightly to Not Accessible
Research history of audits / inspections	94%	34%
Research food safety management plan – can include: Policies and procedures, HACCP plan, SOPs, SSOPs, training records, FDA facility registration, etc.	98%	20%
Research organizational charts, process flow chart	91%	20%
Interview customer – expectations of audit	87%	30%

Develop the Scope of the Audit: how important are these topics?

Answer Options	Important to Extremely Important	Slightly to Not Accessible
Understand product(s) – specialized, imports, recalls	100%	18%
Determine size of facility – square feet/meters	89%	25%
Find out complexity and number of processes/production lines	100%	25%
Note production schedule	96%	27%
Verify number of employees	76%	30%
Pull together an audit team - specialists, number of auditors	89%	25%
Create audit checklists	98%	16%
Be aware of GFSI schemes and their purposes	93%	9%
Determine facility GFSI certification status	93%	11%
Verify terms of certification, if applicable (based on FDA, GFSI scheme or other criteria)	91%	11%

The last three questions for these questions refer specifically to GFSI and are not applicable to FDA inspectors. In addition, checklists are most often created by audit companies and not the auditor/inspector.

Conducting an Opening Meeting: how important are these topics?

Answer Options	Important to Extremely Important	Slightly to Not Accessible
Begin introductions and establish credentials	95%	15%
Discuss scope of the audit	100%	15%
Schedule areas to inspect	100%	17%
Schedule interviews	95%	20%
Review security and safety requirements	100%	15%
Review additional documentation, sampling	100%	15%

All tables: UL EduNeering

Success depends on auditors and inspectors following a prescribed and standardized training curriculum.

It is impossible to calculate the magnitude of savings in human health and food waste if adequate inspections and audits were actually to be performed consistently and competently, however, one can easily imagine the impact would be significant.

The New Food Safety Auditor/Inspector Program

For the past 14 years, UL EduNeering has maintained a unique relationship with the FDA under which it provides the training solution for the agency's Office of Regulatory Affairs online university. More than 36,000 food, drug, and device investigators have used this system. Additionally, FDA and UL have co-developed more than 50 food safety "computer-based training" courses. As a result of the combined experience, NEHA was awarded funding and UL accepted responsibility to produce a collaborative training program engineered to deliver uniformity and competency via a nationally recognized training curriculum for food safety auditors.

While the primary purpose of the Food Safety Auditor Training Curriculum was to support the candidate preparing to sit for the NEHA exam, this curriculum may also be used to raise the competency of any food safety inspector or auditor as it includes instruction on the "art," as well as the "science" of food safety inspections and audits.

Success depends on auditors and inspectors following a prescribed and standardized training curriculum. The successful auditor must have a clear understanding of the knowledge and skills necessary to support various career tracks whether onsite inspector, the audit reviewer, or the audit company management.

While there is common agreement that inspections and third-party auditors represent a needed resource in ensuring food safety, both regulators and food companies also recognize the risks of inconsistent knowledge (competency), experience, and application of those knowledge and skills. As a result, audits and inspections may be inaccurate, inadequate, or incomplete. Mitigating these risks requires a comprehensive program of standardized training and certification that promotes the accuracy and credibility of the audit process that supports responsive actions by companies and regulators.

Assessment of Training Needs

Prior to developing new content for this program, UL researched commercially available courses and performed a gap analysis. Next, a proposed Food Safety Auditor Curriculum (herein referred to as "the Proposed Course") was developed to meet the NEHA Job Task Analysis for Food Safety Auditors and accompanying test requirements, and that filled the content gaps identified. In addition, the new training and certification system will provide support for individuals following various levels of career tracks for auditor/inspector development.

To determine if the Proposed Course meets effective food safety auditor/inspector training needs, a 21 question survey was

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Assessing the Facility: how important are these topics?		
Answer Options	Important to Extremely Important	Slightly to Not Accessible
Walk through - inside and out	100%	24%
Observe processes, log sheets, record reviews, physical facility	100%	27%
Ensure food safety plans are being followed	100%	29%
Confirm personal protective equipment (PPE) is correctly in use	95%	28%
Confirm personal protective equipment (PPE) is correctly in use	93%	29%
Assess tools / equipment, technology	98%	32%
Examine measurements - temperatures, time, pH, etc.	98%	24%
Conduct interviews and assess responses per the food safety	100%	27%
Interview additional employees on the job and assess responses per the food safety plan	95%	28%
Communicate with audit team members	98%	29%
Determine root cause analysis	98%	27%
Validate corrective action processes	100%	27%

Writing an Onsite Summary: how important are these topics?		
Answer Options	Important to Extremely Important	Slightly to Not Accessible
Record observations	98%	20%
Document findings	100%	20%
Perform a risk analysis	88%	27%
Review documents supporting food safety	95%	24%
Review documents supporting food safety	98%	23%

Conducting a Closing Meeting: how important are these topics?		
Answer Options	Important to Extremely Important	Slightly to Not Accessible
Summarize scope of the audit	100%	20%
Review findings	98%	20%
Determine next steps	98%	24%

Writing an Audit Report: how important are these topics?		
Answer Options	Important to Extremely Important	Slightly to Not Accessible
Write an Audit Report	100%	22%
Summarize the scope of the audit, opening meeting, assessment process and closing meeting	93%	22%
Consult with the audit team to assess the success of the food safety system	98%	27%
List critical violations / non-compliances and rank them	100%	17%
Write report according to audit and regulatory requirements	98%	27%
Obtain approval from audit manager	90%	22%
Submit report to the customer's designated stakeholder	93%	20%
Ask for response(s) in a determined amount of time - including a plan of action	98%	21%

Closing an Audit: how important are these topics?		
Answer Options	Important to Extremely Important	Slightly to Not Accessible
Review responses	100%	18%
Determine final steps based on assessment of	100%	18%
Accept or reject documented response	100%	20%
Revisit the non-compliances	100%	18%
Perform a full re-audit if necessary	98%	18%

administered during April and May of 2013, with sub-questions, to food safety professionals and organizations. The goal of the survey was twofold. The first goal was to confirm the importance of the Proposed Course topics, previously determined to be necessary and that are represented in the Proposed Course. The second goal was to identify the current accessibility of the topics to inspectors and auditors.

Study Methodology

The survey was distributed to more than 300 food safety and quality practitioners in regulatory agencies and corporations. In addition, the survey was distributed to 300 additional practitioners who held SQF* (Safe Food Quality) Auditor Certification status.

Approximately 50 qualified individuals responded to the survey, with the following credentials and background:

- Thirty-two participants reported having five or more years of experience as an auditor;
- Forty-two participants reported having experience auditing food processors and food manufacturing facilities;
- Twenty participants cited conducting Global Food Safety Initiative (GFSI) scheme audits as their most commonly performed audit type while 10 participants listed Good Manufacturing Practice and two participants cited "regulatory;" and
- Sixteen participants reported performing the majority of their audit employment as contract auditors while another 15 served as employees of audit companies.

The survey was divided into two primary areas of concern and the participants were provided with the curriculum content outline. One set of questions specifically asked the participant to identify and rank topics felt to be of concern. The second set of questions, the participant was asked to identify the availability of training currently available. Each set of questions allowed the participant to answer the question with the following responses: Extremely Important, Very Important, Important, Slightly Important, and Not Important.

Survey Data Conclusions

The tables (beginning on page 42) provided verification that the Food Safety Auditor/Inspector Training curriculum being developed is a needed service. While one can assess the data points to great length, the one fact that all can agree upon based on the results of this survey is that training for perhaps 65 to 80 percent of the auditors and inspectors today offers the ability to assure competent service providers.

The data gave substantial verification that about 20 to 35 percent of the auditors practicing today feel that vital food safety audit training in nearly each and every topic area addressed by the Proposed Course is either not available or is not readily available to the practice today. ■

Coleman is currently the food safety practice leader with UL EduNeering. Reach him at gary.coleman@ul.com.

**The SQF Program is representative of the GFSI schemes and is one of the primary audit programs used in 2013 by companies operating in the U.S. Neither UL nor NEHA endorse nor recommend either of the GFSI programs nor was either of the scheme requirements or techniques used in the development of this training curriculum. UL has utilized FDA requirements and techniques as the primary focus for development of this training.*

All tables: UL EduNeering

NEW PRODUCTS

Reusable Aflatoxin Affinity Columns

AflaPure Alfatoxin Total and AflaPure Aflatoxin M1 Column Kits can be used up to three times to detect aflatoxin in a variety of food matrices. These ready-to-use columns contain immobilized antibodies that specifically bind aflatoxins, allowing for purification of aflatoxins from sample matrix impurities. The purified samples are ready for sensitive, quantitative analysis using either HPLC or ELISA analysis. The AflaPure Total Column Kit is designed for determining aflatoxins (B_1, B_2, G_1, and G_2) from various food samples including corn, nuts, peanut butter, and spices. AflaPure M1 Column Kit detects aflatoxin M_1 in milk. Each kit includes 25 columns. **Bioo Scientific, 888-208-2246, www.biooscientific.com.**

Food Safety Chain Management System

The next generation version of SafetyChain for Food provides new enhancements to further automate, streamline, and improve FSQA. New levels of granularity have been added to how FSQA processes are defined in the system—including ability to define every criteria, for every test—and associated corrective/preventive actions based upon results. Enhancements can provide more flexibility for the ways in which suppliers, as part of a company's approved vendor program, can upload FSQA documents, do document approval online, fill out/submit forms, and maintain a secure online dialog. In addition, SafetyChain Mobile will now also evaluate safety and quality test results in real time via mobile. **SafetyChain Software, 888-235-7540, www.safetychain.com.**

Lab Management System

NuGenesis Lab Management System provides an alternative to a traditional Laboratory Information Management System. New advances include NuGenesis SampleShare, an optional, secure web-client for sample submissions and results management; NuGenesis Stability, a stability protocol management and testing solution to facilitate a consistent regimented workflow across lab operations; NuGenesis Connectors, a bidirectional link between lab systems and business applications; and Paradigm Scientific Search, an integrated scientific search solution for text, documents, and science objects. Combining synergistic data, workflow, and sample management capabilities to support the entire product lifecycle, the system is a user-centric platform that encompasses a Scientific Data Management System, Electronic Laboratory Notebook, and Laboratory Execution System. **Waters Corp., 800-252-4752, www.waters.com.**

IMS for *E. coli* STEC

Captivate O45 is the newest addition to the Captivate range of immunomagnetic separation products. It comprises magnetic particles coated with specific antibody and is intended for the concentration of *E. coli* O45 from food, animal feed, beverages, pharmaceutical, or environmental samples. The Captivate O45 separates *E. coli* O45 from background flora in a sample, ensuring that only organisms having O45 antigens are captured. Particle-organism complexes can then be easily inoculated to specific microbiological culture media. **Lab M, www.labm.com.**

PCR Assay for Genus *Listeria*

The BAX System Real-Time PCR Assay for Genus *Listeria* can be used as a quick and reliable method for detecting *Listeria* in a variety of products and has been validated on frankfurters, cooked shrimp, spinach, queso fresco cheese, and environmental surfaces. The assay provides additional flexibility by allowing customers to test for both *Listeria* and *Salmonella* in the same batch, with results for both organisms in a little over an hour. **DuPont Nutrition & Health, www.food-diagnostics.dupont.com.**

In Other Product News

Invisible Sentinel's *Veriflow Salmonella* species assay receives AOAC approval.

TransAct Technologies partners with **Neogen** to offer Neogen's AccuPoint ATP Sanitation Monitoring technology as an option on its new Ithaca 9800 food safety terminal.

Roka Bioscience's Atlas *Listeria monocytogenes* LmG2 Detection Assay receives AOAC Performance Tested Methods certification.

InstantLabs enters into an agreement with the **University of Guelph** to co-develop a portfolio of DNA-based seafood species identification tests.

Users of **Thermo Scientific** Dionex UltiMate 3000 series UHPLC and HPLC systems can now drive Thermo Scientific Dionex Corona Veo charged aerosol detectors and Thermo Scientific Dionex UltiMate 3000 ECD-3000RS electrochemical detectors with **Waters** Empower Chromatography Data System.

Food Contract Labs Gobble Up Market Share

An increased amount of food production facilities are sending food samples outside for analysis

By **Catherine Shaffer**

UP UNTIL ABOUT 30 YEARS AGO, ALL FOOD safety analysis was carried out at food manufacturing plants. That began to change when scientists and entrepreneurs realized there was an opportunity to establish food contract laboratories to help food plants meet increasingly rigorous testing and analysis requirements. Over time, companies that began as single-location facilities have grown into larger regional, national, and even international networks.

A report published in March 2014 on the market for food contract labs by Strategic Consulting Inc. (SCI) showed that use of contract labs is increasing in all geographic regions. Revenues for food contract test labs were estimated to have grown from $1.95 billion in 2008 to $3.05 billion in 2013, a compound annual rate of 9.4 percent.

Services offered by contract test labs include microbiology testing for food pathogens, chemistry testing for nutritional analysis, and testing for contaminants like pesticides and toxins. Customers generally get the best results if they use a laboratory specializing in the type of test they are looking for. Lynn Loudermilk, lab director for NP Analytical Laboratories, says NPAL's microbiological service offers a full range of spoilage and pathogen testing, as well as experience in microbial shelf-life and challenge testing. The chemistry group offers testing for macro and micronutrients, including minerals, vitamins, and amino acids to support nutrition in animal health and human food. In keeping with its focus on customer partnership, Loudermilk says NPAL avoids branching out into areas outside its core expertise and works with customers to find labs that perform those services.

Certification and accreditation requirements have driven increased use of contract labs, according to Tom Weschler, president of SCI, particularly in North America. "Meeting requirements is time consuming and cost consuming. As a result, manufacturers are finding it's easier to send samples outside," he says.

Weschler notes contract labs are growing at a rate faster than overall safety testing, indicating contract labs are taking overall market share.

SCI found that midsized food plants tend to make the most use of food contract labs. "It's more difficult for them to afford the overhead, the expense, and the documentation required to run their food plant lab. If you're a larger food plant, you have critical mass," says Weschler. A contract laboratory can also offer the benefit of credibility to testing that, if done in-house, might have the appearance of being biased. ■

Shaffer is a freelance writer based in Ann Arbor, Mich. Reach her at cathshaffer@gmail.com.

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GFSI Delivers Expertise Across Global Food Supply Chain

Experts worldwide collaborate on ways to improve risk management, safety standards, audits, and transparency at annual conference

BY **COR GROENVELD**

Food safety assurance services, including third-party certification, second-party auditing, and training have experienced a boom period in the 21st century. Those changes, which have directly benefited a wide range of stakeholders, first and foremost consumers, but also including retailers, manufacturers, processors, and their suppliers and providers of assurance services, have largely been driven through the Global Food Safety Initiative, or GFSI.

To the general public, the GFSI is a relatively unknown entity, but to its members, the likes of Coca-Cola, Wal-Mart, and Cargill, among others, the GFSI is the engine that drives food safety around the globe. The GFSI's parent organization, the Consumer Goods Forum, hosted the February 26 to 28 Global Food Safety Conference in Anaheim, Calif., with over 1,000 of the world's leading food safety experts attending. Food fraud, assessment, certification, standards, auditor competency, testing, and managing risk were all high on the agenda.

That is a long way from the first Global Food Safety Conference, back in 2001, which had just over 100 delegates and was the first step along the way to bringing food industry retailers, manufacturers, processors, and their stakeholders together. That first GFSI conference took place in Geneva at a time when food safety was making headlines for all the wrong reasons. Large, global companies in the food supply chain realized that the harmonization of food safety standards, sharing of best practice, and more robust assessments of facilities were of paramount importance. At that time, there were over 100 food safety standards, with little oversight as to which ones were the most effective. Most of them were stakeholder owned and managed, thereby bringing their independence into question. Assessors from certification bodies were struggling to keep up with all of the requirements from competing standards, most of which were one day, checklist style "snapshot in time" audits.

One of the first significant steps that the GFSI made following their May 2000 launch was to benchmark existing standards and schemes to bring about a reduction in the number available to the market at large. Further, GFSI members began formulating a more robust approach, moving towards a process-based management systems assessment methodology. This looked more at the documented supporting systems and processes to determine how risk was managed at a facility rather than if, for example, the shop floor was clean at 10:52 on a Tuesday morning.

Throughout its history, the GFSI has listened to their members and stakeholders, even when that feedback raised fundamental questions about key stakeholder groups. An example of this was the opening of the 2011 conference, where the results of a survey that delegates filled in as part of their registration process were shared with the audience. The number one concern for food safety professionals was listed as "auditor competency." This was a clear signal from the users of assessment and food safety certification that it wasn't just the piece of paper on the wall they valued, it was the insight, knowledge, and experience of auditors who understood their clients, the industry in which they operated, as well as the standard or scheme against which they were auditing.

Even at this stage, the leaders of the GFSI knew that addressing auditor competency had to be done with—not to—global certification bodies. The result was the strengthening of the GFSI Technical Committee, with LRQA and DNV being amongst the certification bodies working alongside leading retailers, manufacturers, suppliers, consultants, processors, and academics with a shared objective to ensure that robust assessment was targeted at helping organizations minimize their food safety risks, rather than a return to the pre-GFSI era of certification at any cost.

Three years later and the results are noticeable, with certification bodies and their clients sharing best practice examples with their competitors during the 2014 GFSI Conference, validating the conference theme of "one world, one safe food supply."

Outgoing GFSI board chairman Yves Rey, corporate quality general manager at Danone, lead the GFSI forward—expanding into Asia and broadening the organization's focus to include smaller suppliers and less developed markets as focus audiences. Frank Yiannas, vice president,

food safety for Wal-Mart is also stepping down as vice chair. However, the appointment of Cenk Gürol, group chief SCM officer at Aeon Co., Ltd. and president at Aeon Global SCM Co., as GFSI board chairman, along with Neil Marshall, global director, quality and food safety strategy, policy and programs for The Coca-Cola Company, U.S., and Mike Robach, vice president, food safety, quality and regulatory affairs at Cargill, U.S., as vice chairs of the GFSI, will help ensure a smooth transition in GFSI leadership.

With the 2014 conference now complete and plans for the 2015 Global Conference, which for the first time ever will be held in Asia, in full swing, the results of the GFSI's work are clearly visible. From the original 100 plus standards and schemes, about a dozen are left, with these being regularly assessed by the GFSI Technical Committee to ensure their relevancy. The GFSI's motto "Once certified, accepted everywhere" has had a profound impact in reducing the number of audits that suppliers face, while simultaneously increasing the effectiveness of those audits.

The 2014 Global Food Safety Conference was the largest ever and was led by organizations at the top of the food chain, with speakers from Coca-Cola, Wal-Mart, Danone, Barilla, Mondelez, Mars, Walt Disney, Cargill, and 3M to name but a few of the companies that shared their approach to successfully managing food safety.

The GFSI's mission is to "provide continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide." Over the past 14 years, it has successfully engaged retailers, manufacturers, large and small suppliers, and a range of other key stakeholder groups, proving that the sum is greater than the parts. It is not the GFSI's goal to be a household name, but its work and impact on the lives of consumers is proving a catalyst for change for organizations across the global food supply chain, delivering improved food safety performance, increased confidence in the performance of food safety management systems, and the value of independent assessment of those systems as well as reduced audit duplicity. ■

Groenveld is global head of food supply chain services at LRQA and chair of the foundation for Food Safety Certification. Reach him at cor.groenveld@lr.org.

Advertiser Directory

Events

JUNE

17-18
Food Safety Exchange
Philadelphia, Penn.
Visit www.fse-event.com.

18-20
48th Annual Microwave Power Symposium - IMPI 48
New Orleans, La.
Visit impi.org/symposium-short-courses.

23-24
BRC: How to Interpret the BRC Food Safety Standard, Issue 6
Santa Ana, Calif.
Visit www.scsglobalservices.com/brc-training-issue-6.

24-25
Implementing SQF Training- Ver.7.2
Emeryville, Calif.
Visit www.scsglobalservices.com/implementing-sqf or call 510-452-8003.

JULY

8-9
Dairy Plant Food Safety Workshop
Syracuse, N.Y.
Visit http://sites.usdairy.com/foodsafety.

21-22
HACCP Training
Burbank, Calif.
Visit www.scsglobalservices.com/haccp-training or call 510-452-8003.

AUGUST

18-22
Introduction to Food Science at Rutgers
New Brunswick, N.J.
Visit www.cpe.rutgers.edu/courses/current/lf0201ca.html or call 732-932-9271.

27
Artisan/Farmstead Food Safety Workshop
Ithaca, N.Y.
Visit www.dairyevents.com.

SCIENTIFIC FINDINGS

For access to complete articles mentioned below, go to the "Scientific Findings" section of the June/July issue at www.foodqualityandsafety.com.

ARTICLE: Exploratory Study of Physicochemical, Textural, and Sensory Characteristics of Sugar-Free Traditional Plum Jams

This study was designed to find correlations between the physicochemical–textural–sensory characteristics of sugar-free plum jams, which could prove helpful for the industry to understand the consumers' preferences, to manufacture traditional food products, and to control quality. The qualitative study was conducted on eight sugar-free traditional plum jam samples differing in plum species, geographical area, and processing technique. Good correlation was found between the physicochemical indices and sensory attributes as well as between texture parameters and sensory scores. The electronic nose system was used as a valuable tool for discriminating the samples. ***Journal of Texture Studies,*** **Volume 45, Issue 2, pages 138–147, April 2014.**

ARTICLE: The Effect of Storage on Nutritional, Textural, and Sensory Characteristics of Creamy Ricotta Made from Whey as well as Cow's Milk and Goat's Milk

The aim of this study was to develop a creamy ricotta using a mixture of goat and cow whey as the main ingredients, with the addition of whole goat and cow milk. The nutritional composition, texture, and sensory characteristics of the ricotta cheese were evaluated over 14 days of refrigerated storage. Protein and ash content was decreased and pH changes occurred during the storage periods. The instrumental texture profile indicated that the creamy ricotta was easily deformable, with minimal inelasticity and a cohesive, soft, and delicate texture. Medium- and long-chain fatty acid content was higher than the short-chain fatty acid content. ***International Journal of Food Science & Technology,*** **Volume 49, Issue 5, pages 1,279–1,286, May 2014.**

ARTICLE: *Listeria monocytogenes* in Vacuum-Packed Smoked Fish Products: Occurrence, Routes of Contamination, and Potential Intervention Measures

Contamination of *Listeria monocytogenes* in vacuum-packed smoked fish products at levels greater than the ready-to-eat food limit has been linked to factors such as poor sanitary practices, contaminated processing environments, and temperature abuse during lengthy storage in retail outlets. Intervention technologies have been studied to control spread of contamination. High-pressure processing, irradiation, and pulsed UV-light treatment have shown promising results. Potential anti-listerial effects of some sanitizers and combined chemical preservatives have also been demonstrated. The concept of biopreservation and a combination of different intervention technologies are also being considered. ***Comprehensive Reviews in Food Science and Food Safety,*** **Volume 13, Issue 2, pages 172–189, March 2014.**

ARTICLE: Conservation of Bakery Products Through Cinnamaldehyde Antimicrobial Films

An antimicrobial film containing cinnamaldehyde was developed to pack bread and pastry made without preservatives in this study. These products were wrapped with the antimicrobial films and packaged in low-density polyethylene bags. The antimicrobial activity of the films, the migration of the cinnamaldehyde in the films to the products, and product acceptance by consumers were evaluated. Samples of bread

and pastry packaged with films without the antimicrobial were used as controls. When samples of bread packaged with the cinnamaldehyde films were analyzed, the films were effective in inhibiting the growth of aerobic mesophiles, yeast, and mold. The control sample had twice as much growth compared with the other treatments after 12 days of storage. ***Packaging Technology and Science,*** **Volume 27, Issue 4, pages 293–302, April 2014.**

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