ISSUE 2015-4

NEOGEN NEWSLINE

Breaking News for Food Safety Professionals

Inside this issue:

Food Safety Modernization Act (FSMA) will soon take affect

When President Obama signed the Food Safety Modernization Act (FSMA) into law in 2011, FSMA's 2015 and 2016 compliance deadlines seemed far away. However, now time is growing short for food and beverage companies to adapt the upcoming regulations that aim to strengthen the safety of the food supply.

The proposed rules—which represent the most dramatic overhaul of the U.S. food system in more than 70 years—have established requirements for farmers, food companies and importers to better prevent foodborne illness. With 48 million cases in the U.S. each year, foodborne illness continues to be an important public health problem. Through FSMA, new regulatory and enforcement powers will be given to the U.S. Food and Drug Administration (FDA) to help control the occurrence and better respond to incidents of outbreaks.

According to a recent article, FSMA gives the FDA greater authority to regulate the way foods are grown, harvested and processed, and grants the FDA a number of new powers, including mandatory recall authority, inspection of any and all records in a food-producing facility, authority to require import certificates, suspension of registration, and expanded administrative detention. While two of the rules required by FSMA will be issued August 30, other final rules are not due to be published until October 2015 or later. Compliance will be required with in one to three years, depending upon the business type and size.

In all, FSMA focuses on seven key areas of prevention, and the final deadlines for each are:

- Preventive Controls for Human Food: August 30, 2015
- Preventive Controls for Animal Food: August 30, 2015
- Foreign Supplier Verification Programs: October 31, 2015
- Produce Safety: October 31, 2015
- Accreditation of Third Party Auditors: October 31, 2015
- Sanitary Transportation: March 31, 2016
- Mitigation Strategies for Intentionally Adulterated Food: May 31, 2016

The information that has been released thus far outlines a general approach to preventive controls that begins with identifying all potential hazards associated with each type of food manufactured in a specific setting. Establishing and implementing written procedures to monitor these potential hazards, along with developing corrective action requirements are also both a part of the new law. Developing verification requirements that validate the preventative controls and verify that correct actions are talking place when needed, among other things, are also written into FSMA.

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> *FSMA, continued from front page*

In addition, food safety plans must be reanalyzed and updated every three years at a minimum and according to FSMA, environmental monitoring—which ties in hygiene monitoring, allergen controls and testing for foodborne pathogens—is also a large part of the new law.

Supplier controls, which aim to strengthen the food safety system even further back in the process, requires onsite audits and raises the bar for entry of products coming into the U.S. as well as shifts accountability to importers.

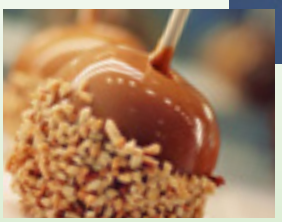
In May of 2014, the FDA released an operational strategy document laying the framework and guiding principles for its implementation activities. It emphasized the FDA's intention to rely on traditional and new oversight tools, including: education and outreach to industry, technical assistance to facilitate compliance, regulatory incentives for compliance, public education, transparency, and publicity to promote compliance and prevention. However, questions regarding how several new regulations will be implemented, and what the FDA will do to verify compliance, still remain.

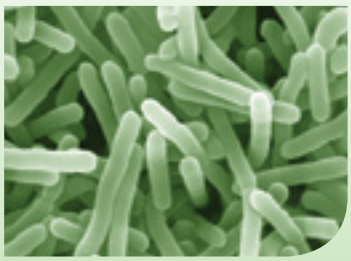
Advanced technology tracks *Listeria* through DNA sequencing

Genetic epidemiology is changing the detection of foodborne illnesses, according to a new study performed by the U.S. Centers for Disease Control and Prevention (CDC) in which researchers have sequenced the DNA of every *Listeria* sample tied to an illness in the United States—about 800 per year.

"Now that we're turning whole-genome sequencing on, we're identifying outbreak after outbreak and finding smaller outbreaks that we were unable to find before. They're also finding them originating in previously unsuspected foods, from caramel apples to ice cream," Brendan Jackson, a medical epidemiologist with CDC, said in a recent article.

In fact, DNA sequencing is what finally cracked the recent *Listeria* outbreak, in which three people died and many others were hospitalized. As stated in the article, Infection Prevention and Control Coordinator, Kären Bally had been searching for anything to tie together the infections, which started with a single illness in January 2014.





Unfortunately, traditional epidemiological tools showed nothing. Diet records were inconclusive, and *Listeria* samples from the first four patients seemed unrelated using the standard technique for DNA analysis.

Then, when the fifth patient fell ill in early 2015, DNA analysis finally showed a link to a previous case. A sample was sent to the CDC for confirmation and whole-genome sequencing revealed that the two samples were a near-perfect match.

The FDA was contacted, having just sequenced tainted ice cream samples from a facility where inspectors had discovered *Listeria*. When they compared those results to the CDC samples, they found another match. The CDC then looked into other unsolved *Listeria* cases and by sequencing samples still in storage, they confirmed five additional cases, dating back to 2010.

"It's not something that we've seen before—being able to look at cases so far back," Jackson said in the article. "Although it took many tools to track the current outbreak, whole-genome sequencing made all the difference."

Previously, investigators relied on diet interviews and genetic fingerprinting as their two main tools for tracking foodborne illness cases. According to the article, fingerprinting shows the degree to which two different samples of DNA are related but it is not 100% accurate. In some cases, different bacterial strains can appear related and similar strains can appear to be unrelated.

In contrast, whole-genome sequencing, allows scientists to accurately compare every single DNA base pair in samples, giving them "a much sharper look at the differences and similarities in the strains," Jackson said. The process takes 72 hours for testing, which is about 24 hours longer than fingerprinting and costs more as well.

However, results are showing that this technique is much more reliable.

For example, from 1983–1997, the U.S. detected only five *Listeria* outbreaks. Then in 2004, the agency introduced its "*Listeria* initiative," an enhanced surveillance system for *Listeria* infections, and the average number of outbreaks detected each year rose to 2.9.

Finally, in 2014, many health departments around the country began adopting whole-genome sequencing and in that year alone, the agency counted nine *Listeria* outbreaks.

"It's not that we're experiencing more *Listeria* outbreaks today than in the 1980s," Robert Tauxe, deputy director of CDC's Division of Foodborne, Waterborne, and Environmental Diseases, said in an article. "We're simply getting much better at finding them."

The CDC's goal now is to create a national DNA database for foodborne pathogens from clinical samples that could be integrated with an already-existing FDA database of foodborne pathogens from food and environmental samples.

"Whole-genome sequencing shines a new light in this area that helps us find unsuspected gaps in the food safety system," Tauxe said in the article.

For more information, click here.

Neogen Corporation is a leader in developing and marketing test kits that provide food safety solutions including those for *Listeria*. For more information, click here.

The importance of environmental monitoring in food production facilities

Environmental monitoring in food production facilities is becoming increasingly important as the finalization of the Food Safety Modernization Act (FSMA) looms on the horizon and the deadlines for compliance draw near. As a whole, environmental monitoring contains several aspects including hygiene monitoring as well as monitoring for pathogens and allergens. Together all of these aspects are of critical importance to the overall safety of our food supply.

A recent article breaks down hygiene monitoring, and describes it as testing the cleanliness of the plant environment, and thereby assessing the effectiveness of the facility's cleaning processes. The article states that one of the most common tests used to gage cleanliness is one involving the testing for Adenosine triphosphate (ATP). ATP is a molecule found in all living cells; thus, in and of itself, ATP is not a hazardous contaminant. However, detection of its presence after equipment has been cleaned is an indicator that food, bacteria, or other organisms have been left behind and the cleaning process was not sufficient.

That being said, ATP hygiene monitoring systems have become a standard in measuring the effectiveness of cleaning efforts in the food production industry. Although they have been around more than 20 years, ATP testing aligns with FSMA's overarching theme of prevention rather than reaction in order to reduce the number of food related recalls and instances of foodborne illness outbreaks in the U.S.

The article goes on to state that when it comes to ATP testing within FSMA regulations there will be a greater importance placed on formal verification and validation of the hygiene monitoring system that is in place in the facility's sanitation standard operating procedures (SSOP). In addition, formal documentation of all the food safety systems in place will be a major component to all control programs within FSMA.

While hygiene monitoring is extremely important, it is only one part of a proper environmental monitoring program. Food allergen and pathogen control measures are additional aspects that cannot be over looked as they provide a holistic and disciplined approach to avoid failures in environmental monitoring programs that otherwise could result in allergen-related recalls and outbreaks of foodborne illness.

With multiple opportunities for cross contamination and adulteration, food allergen testing is crucial in any food production setting. Testing should be implemented through an allergen control plan, which as described by the Food Allergy Research and Resource Program (FARRP), is a company's written document regarding the storage, handling, processing, packaging, and identification of allergenic foods and ingredients. This gives producers not only confidence in the ingredients used, but also in the quality of their final products. An allergen control plan is a critical component in product safety initiatives and is a team effort that must be developed and implemented as a system.

In addition, all areas of a food producing company should be involved in the allergen control plan. For example, quality assurance can coordinate the program while other areas including research and development, purchasing, production, shipping and receiving, labeling, warehousing, sanitation and human resources must all be integrated into the program as well.

For each operation within the facility where allergens are handled or used, it is imperative that there be documented procedures describing when to test, how to test, and recommendations for testing frequency. Additionally, how to monitor, verify compliance with regulations, and what to do in the event of an outbreak, are all equally important factors to be covered in an allergen control plan.

Furthermore, monitoring for pathogens is another critical element of any environmental monitoring program and a similar plan to that of allergen control must be implemented in any food producing environment. Controlling for pathogens including *E. coli*, *Listeria*, *Listeria monocytogenes*, *Salmonella* and *Staphylococcus aureus* involve microbiological testing of finished products as well as their ingredients and any surfaces they come in contact with, and are all of critical importance in any food producing facility.

According to the Food and Drug Administration (FDA) a prevention-based safety approach such as the HACCP system (Hazard Analysis Critical Control Points) can help identify and monitor any food safety hazard that may occur during the processing of food, including the pathogens mentioned above. This system gives those in the food industry confidence that food safety is being managed effectively and ensures that personnel are well trained and able to make necessary decisions in this arena.

By identifying where hazards are most likely to occur in the operation, it is much easier to put in place the measures needed to prevent those hazards. While there are several steps to implementing this type of system, the overall plan must be tailored to the specific processing facility and continually be updated and verified in order for it to be the most beneficial.

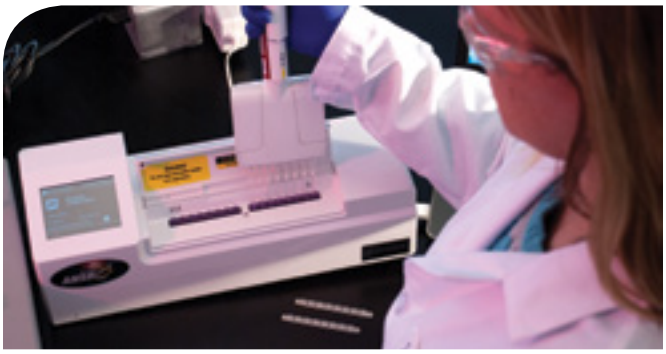
As with any monitoring program, commitment from management and proper training are of critical importance in order for any food safety program to be as successful as possible. As stated previously, each facility may have a different plan based upon their equipment and processing requirements but in all, producing a safe product is the end goal. This can only be achieved through a complete environmental monitoring program that takes into account hygiene monitoring as well as allergen and pathogen control.

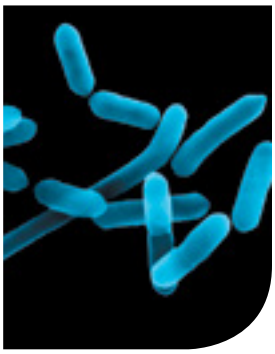
Neogen's ANSR® for *Listeria monocytogenes* receives AOAC approval

Neogen has received approval from the AOAC Research Institute for its new rapid and accurate test to definitively detect *Listeria monocytogenes* DNA in food and environmental samples.

Neogen's newly approved ANSR® for *Listeria monocytogenes* (Performance Tested Method℠ certification, No. 061506, from the AOAC Research Institute) detects *L. monocytogenes* after only 10 minutes post-sample processing. Neogen's ANSR is an isothermal amplification reaction test method that exponentially amplifies the DNA of any target bacteria present in food and environmental samples to detectable levels.

"The AOAC approval further validates our test as an invaluable tool to food producers," said Ed Bradley, Neogen's vice president for Food Safety. "ANSR is the fastest DNA-definitive pathogen assay available—with results in only 10 minutes. Compared to the three hours other methods such as polymerase chain reaction, or PCR, take to produce DNA-level results, that's a huge difference in a laboratory's workflow, and the operations of a food producer as a whole."





Combined with ANSR's single-step enrichment, Neogen's new pathogen detection method for *L. monocytogenes* can provide definitive results in as little as 17 hours for environmental samples from the time the sample is taken. The new test also utilizes Neogen's LESS Plus Medium, which can be autoclaved—allowing for larger batches of media to be prepared prior to use.

The approval covers the use of the ANSR system to detect *L. monocytogenes* in the following representative sample types: hot dogs, Mexican-style cheese, cantaloupe, guacamole, pasteurized liquid egg, sprout irrigation water, and sponge samples from stainless steel surfaces.

Neogen's line of ANSR products also includes AOAC Research Institute-validated ANSR for *Listeria* and ANSR for *Salmonella*.

Neogen offers an unmatched industry-specific range of microorganism testing products, experience and expertise—from lateral flow immunoassays to fully automated pathogen and spoilage organism platforms, to a comprehensive catalog of high quality dehydrated culture media, to DNA genotyping technology through its NeoSeek™ genomic profiling and serotyping service.

Want to learn more about Neogen?

Neogen is an active participant and sponsor of numerous large and small industry associations, across our many market segments. As such, we attend numerous tradeshows throughout the year. Please stop by our booths to learn more about what we have to offer, and more importantly, to help us better serve your industry.

Quality Chekd (QCS)
September 14–15 • Chicago, IL

International Dairy Show
September 15–18 • Chicago, IL

Organic Expo
September 17–19 • East Baltimore, MD

Food and Pet Food Joint Conference
September 21 – October 2 • Chicago, IL

World Dairy Expo (WDE)
September 29 – October 3 • Madison, WI

Supply Side West
October 7–8 • Las Vegas, NV

@neogencorp on Instagram!

Neogen Corporation is now on Instagram, featuring the latest and greatest images from around the company.

And for the latest food safety, animal safety and life science news, Neogen announcements and useful information, check out the Neogen blog at www.neogen.com/blog

Researchers study science behind drug resistant bacteria

Klebsiella pneumoniae strains of bacteria, or those better known as being resistant to antibiotics, are the focus on a new study where scientists are using genome sequencing capabilities to find out how exactly antibiotic resistant strains of bacteria come to be.

The scientists have already identified several mechanisms that bacteria use to share genes and expand their antibiotic resistance. In fact, they found that in some cases bacteria can receive a new set of genes all at once and in the process become pathogenic.

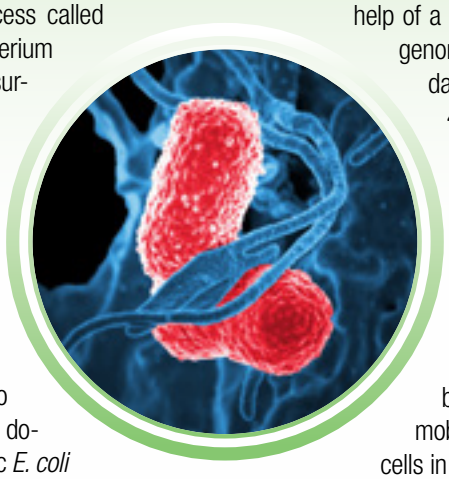
As explained in a recent article, the scientists involved in the story are focusing on the large mobile DNAs, such as plasmids, which exist as free DNA circles apart from the bacterial chromosome, and genomic islands, which can splice themselves into the chromosome. These mobile DNAs are major mechanisms for evolution in organisms that lack a true nucleus. Genomic islands and plasmids carry genes that contribute to everything from metabolism to pathogenicity, and move whole clusters of genes all at once between species.

"Identifying how genomic islands move and their effect on bacterial physiology could lead to new approaches to bypass bacterial defenses," researcher Corey Hudson of Sandia National Laboratories in California, said in the article.

Eventually, the hope is that their effort might lead to a way to predict new pathogens before they emerge as public health threats.

"We're just starting on this path," researcher Kelly Williams said in the article. "It's a harder problem to predict emerging pathogens, rather than just observe them. Determining what is pathogenic in the first place and how it might become more pathogenic is a research challenge."

For some background, Williams said that it's important to understand that bacteria share genetic material through free virus particles or through a cell-to-cell process called conjugation, where one bacterium sends out a tube from its surface into another's and injects genes into the other cell.



For example, consider you have a local water supply that is contaminated with a pathogenic *E. coli* strain that is not antibiotic-resistant. *Klebsiella pneumoniae* enters the water, comes into contact with the *E. coli*, and donates genes. Now a pathogenic *E. coli* has acquired resistance, making it harder to eradicate.

This type of research could be crucial in the food safety industry as the number of U.S. food products recalled—and the costs associated with those recalls—have nearly doubled since 2002, according to a recent report.

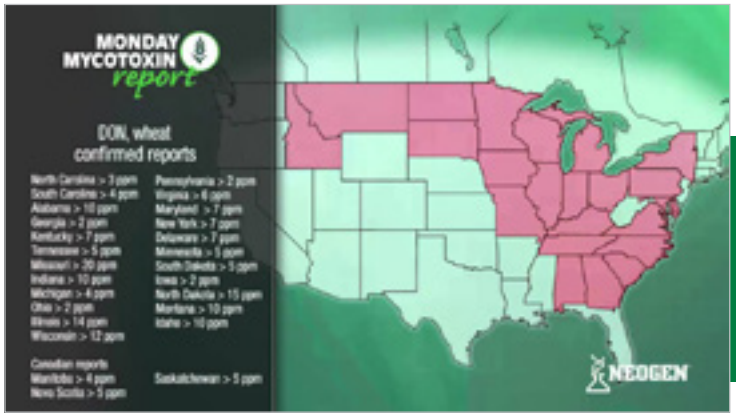
Among other things, the increasing number of recalls can be explained by a combination of regulatory changes and the advent of an increasingly globalized food supply chain.

At the same time, the portion of the U.S. population which is sensitive to pathogenic contamination and allergenic ingredients in food is growing, making the prospect of selling risky food even shakier, the report states.

The team's research will continue with the help of a database they created of genomic islands. So far, the database contains nearly 4,000—only a partial list.

To go along with this, the team also invented a new experimental approach to detect islands as they pop out of the genome. The team stimulates this beginning stage of island mobilization by stressing the cells in certain ways. During this stage, the mobilized islands take circular form, independent of the chromosome. The islands are now free to move into other bacterial cells, bringing with them new sets of genes.

For more information, click here.



Neogen's Monday Mycotoxin Reports are back! Each week, we are happy to present to you an up-to-date report, sharing data and statistics from the agriculture industry. To watch, visit our YouTube channel (www.youtube.com/neogencorp), or follow the links on our blog and social media sites: www.neogen.com

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