Latest trends and breakthroughs in food pathogen analysis

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The global food microbiology testing market is estimated at $3 billion with almost one billion tests performed annually. The analysis of food pathogen targets such as salmonella, listeria, E. coli O157 and campylobacter account for $1.4 billion or around 224 million tests of the food microbiology market, which is a 30% increase since 2008.

While the EU is using 50% traditional methods and 50% rapid methods, the US primarily uses rapid methods including antibody-based lateral flow devices and ELISA plates and molecular methods such as PCR. Asia and the rest of the world mainly continue to use traditional cultural plate methods (Strategic Consulting 2013).

Globally, 50% of the tests performed are conducted in finished products, 40% on in-process or environmental testing.

In North America the focus is more on environmental and in-process testing, whereas Europe and Asia are mainly focusing on finished product testing with little environmental monitoring.

Healthy growth in testing

After a decade of solid but quiet growth, the microbiology testing requirements of the food processing industry – especially in pathogen testing – have been thrust into the public spotlight again, driving healthy growth in food diagnostic testing.

Overall market value growth has averaged 13% over the past three years and pathogen testing market value has averaged 18% during the same time. While food companies continue to make investments in their overall food safety programs, new regulations, outbreaks, and public concern drive even more pathogen specific testing.

Pathogens are everyone's focus. As a result, new diagnostic technologies and new players are entering the market, and the business landscape is continuing to change through acquisitions, partnerships, and new product offerings.

When the science of microbiology was in its early stages of development, scientists used liquid culture media for the cultivation of micro-organisms. Agar revolutionised the science of microbiology as it made what had been a difficult task of separating and culturing micro-organisms on solid surfaces a routine procedure.

Interestingly, over 100 years later, all microbiology laboratories, in every industry sector, continue to use agar as the most important and widely accepted material for growing micro-organisms today.

These traditional cultural microbiology methods typically require trained microbiologists to interpret results and call for 48-72 hours enrichment incubations.

Current rapid method technologies can detect the presence of food pathogens by various techniques dependent on the specific technology and instrumentation employed.

These methods require that the sample still be enriched in a liquid media to grow the target pathogen to a detectable level. The primary rapid microbiology detection platforms used in the food industry today are antibody-based platforms such as lateral flow devices or ELISA-based methods and molecular-based platforms such as PCR methods.

Laboratories chose these rapid methods over the traditional cultural methods because they provide a much faster time to result (8-24 hours), are easier to use and interpret results and provide economical high throughput screening.

Food industry perspective

The food industry must use pathogen detection methods that are reliable and consistent in their performance. Currently, multiple rapid method platforms are in use including immunological and genetic platforms. The data generated by these methods must also be defendable with regulatory bodies. A fast time to result is important, but cannot compromise the accuracy of the methods.

Rapid methods are a very good screening tool, as they are cost effective and deliver results faster than traditional cultural methods. However, 'fit for use' verification of these methods is absolutely necessary prior to adopting a specific technology.

Food testing laboratories typically work with rapid method developer to determine how a protocol is validated for the particular sample type and application and whether

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field performance studies are required to verify method performance.

One hurdle for the food industry laboratory is that more structure is needed for these validation studies. Each rapid test kit manufacturer designs validation studies differently and there is no uniform standard which makes it difficult to interpret data, compare methods and apply them to real-world applications.

An on-line, up-to-date summary of a method's validation data and product claims as well as in-house validations and special studies would also help laboratories compare rapid test methods for use in specific applications.

Time-to-result is the test method feature that most laboratories would like to improve upon; however, it is important to maintain performance and ease of use characteristics.

Regulatory perspective

From a general regulatory view, results generated from rapid food pathogen method must be unequivocal in nature (no misunderstanding, or misinterpretation). For example, real-time detection methods are favourable for the USDA FSIS with dependable outcomes that are very repeatable. These agencies are also interested in real-time systems that are fast, accurate, and practical to implement.

Many regulatory agencies are looking to develop guidelines for method validation protocols and databases of validated methods to aid industry in selecting the appropriate methods. A future area of focus for the US-based regulatory agencies is whole genome sequencing.

Whole genome sequencing offers great opportunities for outbreak investigations, but also risk assessment. These technologies and their applications are currently developed and studied at the academic levels and some interactions and case studies have been initiated with the food industry in order to demonstrate their input in regards of food safety issues and risk management.

Future trends

● Sample preparation and workflow

Because food pathogen detection methods still require a lengthy enrichment step, sample preparation and method workflow are key areas of improvement for rapid pathogen methods.

Time to result remains the key issue and improved enrichment or non-enrichment methods with good workflow and data management capabilities are required.

Possible improvements in the sample enrichment include fewer broths or more universal broths for multiple pathogens, reduced enrichment volumes and fewer hands-on steps. Universal sampling, enrichment broths, and workflow will streamline testing in laboratories where multiple pathogens are analysed.

A database listing all the methods for sample preparation is desirable given the high diversity of matrices involved for pathogen testing.

● Detection of genes, species and serogroups

Over the past three years, scientists at the US Food and Drug Administration have conducted whole genome sequencing on hundreds of foodborne pathogens to get a detailed map of their DNA.

The initiative, entitled 'The 100K Genome Project', is a private-public collaboration between FDA, the University of California Davis and Agilent, hopes to expand that figure to 100,000.

By developing this new database, regulators hope to help health officials cut down on the time it takes to identify the source of an outbreak. The debate over the value of genome sequencing versus serotyping is still ongoing. In reality, both detection technologies provide valuable information.

For gene detection using molecular rapid methods, the main challenges are to find the right combination of targets as well as understanding the virulence of the genes that are being targeted.

Trying to connect the gene targets to disease virulence, will require the regulations to evolve in regards to detection technology and their reliability.

There is an increasing amount of environmental monitoring for the preemptive control of food pathogens in the food processing environment. Environmental monitoring is an ongoing process of sampling and testing that measures the effectiveness of the contamination control measures, such as sanitation practices, in a plant.

An effective monitoring program is a critical component to measuring the overall effectiveness of the microbiological controls that are in place. Listeria species is used as an indicator of contamination control in refrigerated, wet-processing environments typically found in ready-to-eat meat processing plants.

Salmonella species is used as an indicator of contamination control in low-moisture processing environments typically found in other types of ready-to-eat food processing plants. However, there is limited data on the effectiveness of some environmental monitoring programs and its prediction of risk and control will depends upon the specific product/process/plant under consideration.

● Emerging pathogens

Currently, food pathogen targets such as salmonella, listeria and E. coli O157 account for over 93% of the 224 million pathogen tests performed globally. However, there are new emerging threats that have the attention of the food industry, test manufacturers and regulators.

These threats include foodborne viruses such as norovirus and hepatitis A and E, parasites such as Cyclospora and Giarda, Staphylococcus aureus, and non-top 6 STEC such as E. coli O104.

There is an increasing concern in new and emerging pathogens that are antibiotic resistant. Of particular concern for food are strains of salmonella that are resistant to antimicrobial agents and have become a worldwide health problem.

Multi-drug resistant (MDR) salmonella continues to pose a public health threat, particularly as resistance spreads across classes of drugs, necessitates the use of more expensive drugs, makes treatment less effective, and, in worse case scenarios, leaves infections untreatable.

Couple the MDR strains of bacteria with the unknown risk that pathogens from developing countries might be reintroduced to the developed world through importation, will necessitate that the global food supply chain needs increased monitoring. ■

This information is summarised from the Future Technology and Innovation Forum organised by Romer Labs at the 2013 IAFP Meeting in Charlotte, NC, USA, addressing the trends and breakthroughs in food pathogen analysis. Key opinion leaders from the food safety arena, including food business operators, regulatory agencies, analytical service laboratories, food safety academics and food safety consultants were invited. These parties discussed and reviewed the current state-of-the-art technologies and future needs in foodborne pathogen detection, as well as regulation implications and the most recent information on foodborne pathogen behaviours (epidemiology, at-risk food products, pathogenicity and virulence factors).