EDUCATIONAL COMMENTARY – PROFICIENCY TESTING IN FOOD MICROBIOLOGY LABORATORIES

Educational commentary is provided through our affiliation with the American Society for Clinical Pathology (ASCP). To obtain FREE CME/CMLE credits click on Earn CE Credits under Continuing Education on the left side of the screen.

LEARNING OBJECTIVES

On completion of this exercise, the participant should be able to

- discuss proficiency test performance in food microbiology laboratories.
- compare and contrast federal regulation of food microbiology and clinical microbiology laboratories.

Commentary

A critical component of the strategy to ensure a safe food supply is analysis of food samples to detect pathogens that cause foodborne illness. As in clinical laboratories, performance on proficiency test (PT) samples is an indicator of how well food microbiology laboratories perform with real samples. Unlike clinical laboratories, few studies have examined PT performance in food microbiology laboratories, and most published studies analyze data from European food PT programs. Also, although both clinical laboratories and food-testing laboratories perform testing directly related to individual and public health, the regulatory environments that govern the two types of laboratories differ greatly.

Proficiency Test Performance in Food Microbiology Laboratories

One study analyzing PT performance in food microbiology laboratories in the United States examined qualitative data from 1999 to 2007 from PT provider American Proficiency Institute (API). The data revealed that food microbiology laboratories often fail to detect pathogens in PT samples, which suggests that they often fail to detect pathogens in samples of real food. Specifically, the nine year cumulative false-negative rates in API’s data were 5.9% for *Salmonella* species, 7.2% for *Listeria monocytogenes*, 7.8% for *Escherichia coli* O157:H7, and 13.6% for *Campylobacter* species. Low concentrations of bacteria and atypical strains were most likely to be missed. For example, 24% to 30% of laboratories failed to detect unusual strains of *Salmonella*, and the failure rate for one sample containing *Campylobacter coli* was 24%.

In a poster session at the American Society for Microbiology General Meeting in June 2012, API presented updated PT data obtained through 2011. In this analysis, the cumulative 13-year failure rates for specimens containing pathogens declined slightly, but they remained above 5% for all four pathogens.
EDUCATIONAL COMMENTARY – PROFICIENCY TESTING IN FOOD MICROBIOLOGY
LABORATORIES (cont.)

As was true with the published nine year data, the poorest performance occurred with samples containing Campylobacter, followed by E. coli O157:H7, L. monocytogenes, and Salmonella.

Regulation of Clinical and Food-Testing Laboratories

Clinical laboratories are regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88), a series of federal laws designed to assure reliable results in all laboratories that test patient samples. CLIA ’88 requires laboratories to be licensed, and the requirements for licensure depend on the complexity of the tests a laboratory performs.

Clinical laboratories performing moderately to highly complex testing are mandated to successfully participate in an approved PT program. CLIA ’88 stipulates the number of PT events per year, the number of challenges per event, the minimum performance level, and actions to remedy unsuccessful performance. Specifically, each regulated analyte must be tested in at least three PT events per year, with at least five challenges per event. For most analytes, successful performance requires 80% satisfactory results; for ABO group, Rho(D), and compatibility testing, the requirement is 100%. Laboratories that fail two consecutive events or two of three events must stop testing patient samples for that analyte until they demonstrate satisfactory PT performance. Laboratories that fail to maintain successful PT performance can face severe sanctions, including loss of licensure.

By contrast, food-testing laboratories are not currently regulated by federal law. Laboratories may seek accreditation, but it is voluntary. If a laboratory chooses to become accredited, it must meet ISO/IEC standard 17025, General requirements for the competence of testing and calibration laboratories. The ISO standard requires participation in a PT program, but accrediting agencies may differ in how they interpret this requirement. In general, accrediting agencies in the United States require participation in one event per year, with a minimum of two PT samples per analyte. If an accredited laboratory fails a PT event, it must take corrective action and pass the next available PT event. If a laboratory does not take corrective action, it risks its accreditation. However, even when a laboratory fails multiple PT events, it is not required to discontinue testing samples of real food.

For non-accredited laboratories, participation in a PT program is voluntary. Likewise, non-accredited laboratories that participate in PT but fail an event are not required to take corrective action or to stop testing real food samples.

Food Safety Modernization Act

Recognizing that existing laws did not adequately regulate food production and distribution activities, the United States Congress passed the Food Safety Modernization Act of 2010 (FSMA), which was signed
EDUCATIONAL COMMENTARY – PROFICIENCY TESTING IN FOOD MICROBIOLOGY LABORATORIES (cont.)

into law in January 2011. The FSMA amends the Federal Food, Drug, and Cosmetic Act and gives the Food and Drug Administration (FDA) greater powers to require and enforce practices intended to prevent outbreaks of foodborne illness. The enforcement powers in the FSMA aim to achieve four goals:

1. Improve compliance with prevention and risk-based food safety standards.
2. Require food producers to use preventive food safety systems.
3. Enhance the FDA’s ability to monitor food safety systems.
4. Improve the FDA’s ability to detect and contain problems.

Some aspects of the FSMA, such as the FDA’s authority to order mandatory recalls of tainted food, went into effect immediately. Also, beginning October 22, 2012, domestic companies are required to register with the federal government and reregister every two years. Initially, however, the provisions in the FSMA will be directed at imported food. The ultimate responsibility for ensuring that imported food meets U.S. food safety standards will fall on the importer, rather than the producer.

The FSMA stipulates deadlines that the FDA and the Office of Management and Budget (OMB) must meet in order to fully implement the provisions of the new law. However, the FDA and OMB have missed a number of key deadlines, including issuance of the final rules that will affect food-testing laboratories. Among the issues awaiting clarification is a requirement that certain food-testing laboratories be accredited. Because the final rules have not been published, it is not yet known exactly how the FSMA will affect food microbiology laboratories.

Reasons for the delay in publishing the final rules are unclear, but they may include concerns from trading partners such as the European Union, the potential cost to small businesses, or the complexity of the law itself. Regardless of the reasons, both the food industry and consumer groups are pressuring the government to release the rules. In August 2012, the Center for Food Safety and the Center for Environmental Health filed a lawsuit to compel the FDA to enact FSMA regulations by a court-imposed deadline.

Conclusion

Modern food production methods, widespread dissemination of food products, rapid transportation of food and people, changes in eating habits, and the emergence of new pathogens have changed the epidemiologic characteristics of foodborne disease. For example, food that is shipped to multiple locations throughout the country can cause outbreaks of illness in large regions rather than in a single
EDUCATIONAL COMMENTARY – PROFICIENCY TESTING IN FOOD MICROBIOLOGY
LABORATORIES (cont.)

community. The pathogens implicated in foodborne disease are often not the same organisms commonly implicated a half century ago. For example, noroviruses, rotaviruses, Cryptosporidium, Campylobacter, and E. coli O157:H7, major causes of foodborne disease today, were unheard of as recently as the mid 20th century.  

Food microbiology laboratories play a critical role in preventing outbreaks of foodborne disease, but PT data suggest that they may often fail to detect pathogens in food. Although food-testing laboratories are currently unregulated, this may soon change when the final rules to implement the FSMA are published.

References


© ASCP 2012