

The Food Safety Modernization Act – A Series on What is Essential for a Food Professional to Know Article 7. Laboratory Accreditation

ABSTRACT

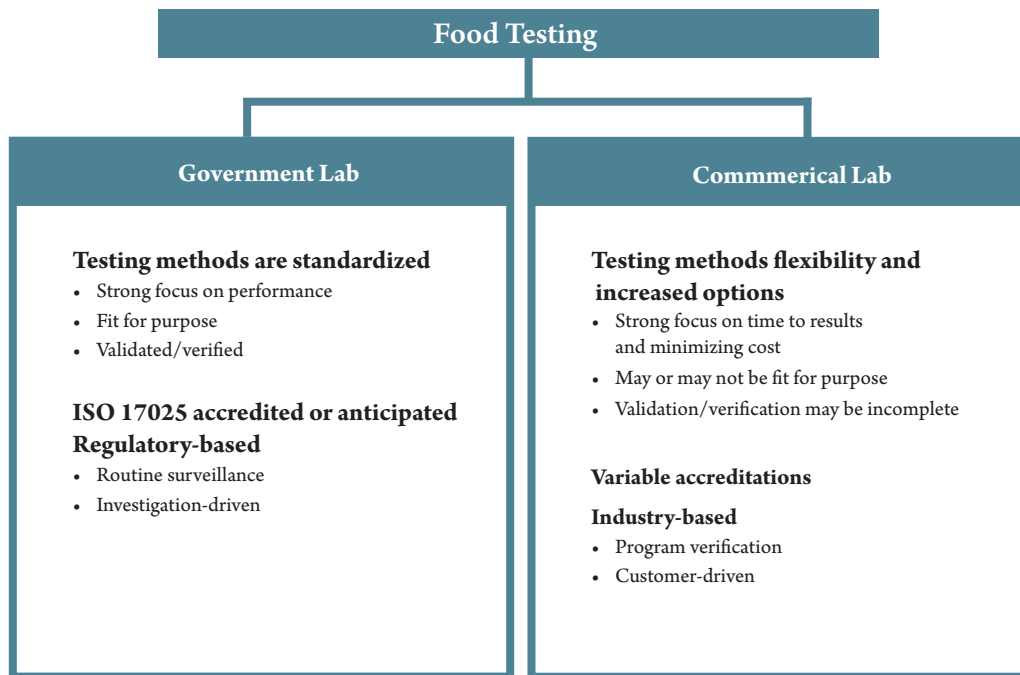
The FDA Food Safety Modernization Act (FSMA) is a significant and far-reaching update of the laws and subsequent regulations that affect the safety of foods regulated by the United States Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides FDA with greater powers and directs the agency to develop regulations that will focus the food industry on the prevention of foodborne illness, instead of the historical reactionary approach. This document is the last in a series of articles describing the legal fundamentals for food professionals and focuses on the provisions within FSMA that apply directly to laboratory accreditation, as FDA increases domestic and foreign laboratory capacity surrounding the sampling and testing of food products. The current understanding of the rule and applicability to the food testing industry, in general, is discussed.

INTRODUCTION

The FDA Food Safety Modernization Act (FSMA) is the first update to antiquated U.S. food safety laws in more than 70 years. FSMA and its subsequent regulations aim to improve the safety of domestically produced and imported foods regulated by the U.S. Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides FDA with greater powers and directs the agency to develop regulations that will allow the food industry to prevent the on-going problem of foodborne illness. In America, it is estimated that 1-in-6 people will contract a foodborne illness, causing 125,000 hospitalizations and 3,000 deaths each year (2).

This document is the last in a series of articles describing the legal essentials within FSMA, pertinent for food professionals. Previous articles in this series have reviewed implemented provisions, preventive controls, food defense, produce safety standards, foodborne illness surveillance, and imported food, under the context of the new law. This final article focuses on the provisions within FSMA, as shown in *Table 1*, that apply to accreditation of laboratories that

*Author for correspondence: E-mail: wwarren@aegisfoodlabs.com



The goal of every lab should be reliable results, which are achieved by proper sampling, sample preparation, test method utilization, technician competence and strong ethics.

FIGURE 1. Overall dynamics of the food testing industry.

conduct sampling and food testing for regulatory purposes. It also draws attention to other provisions in FSMA that have an impact on laboratory accreditation.

Laboratory accreditation offers a mechanism to support the generation of reliable data, based on a structured and independently verified quality assurance program. When combined with meaningful sampling plans, properly trained and competent laboratory technicians, scientifically sound analytical procedures and ethically responsible management personnel, it should ensure that associated laboratory data are accurate and reproducible. Such data serve as an important tool in supporting informed decisions about the safety and quality of direct human contact items, including food, pharmaceuticals, dietary supplements, drinking water, environmental samples, cosmetics, toiletries, household items, and toys.

A variety of accreditation programs exist, with guidance on best practices, available to both regulatory and commercial laboratories. Testing method guidance is based on the item or items to be tested and the purpose for and/or intended recipient of the data. Since regulatory agencies typically do not have legislative authority over private laboratories, there is opportunity for a broad range of interpretation and implementation in the technical analysis conducted, as well as reporting of associated data – unless the testing is conducted directly for regulatory purposes and prescriptive procedures are available. While the FDA Office of Regulatory Affairs interacts with and provides expectations for private laboratories via imported food items and mandated compliance with the Food, Drug, and Cosmetic Act as part of the detention without physical examination program, laboratory accreditation is not currently specified under either. Rather, it is the responsibility of the importer to ensure that the laboratory is providing technically sound and reliable data.

In the event FDA questions the integrity of the sampling and/or testing program, FDA is authorized to conduct on-site visits and review laboratory procedures. However, this type of action would not be considered an “official inspection” by FDA and participation by the private laboratory is considered voluntary (4).

It is important to draw a distinction between commercial (or private) food testing and testing conducted for regulatory purposes. (See Fig. 1 for an illustration of these differences.) The majority of food testing performed in the U.S. is considered private in that it is initiated by industry as a tool to verify the effectiveness of food safety programs, such as Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practices (GMPs), microbial intervention programs, raw material supplier performance, sanitation programs, and/or environmental control programs. Such testing often occurs internally within a company-owned laboratory or by a third-party commercial laboratory. In this case, testing data are used to make various process-associated decisions ranging from the effectiveness of a sanitation program, to product disposition, to compliance with customer expectations. Commercial testing encompasses a variety of procedures with differences largely based on cost, turn-around time, and validated performance.

Independent of commercial testing is regulatory testing, which is driven by routine surveillance programs or foodborne illness investigations. Regulatory testing is most often conducted by federal- and state-level government laboratories following standardized procedures, but may occur at a private laboratory under specific, contracted procedures. Regulatory testing methods are most often performance-driven.

While government laboratories have already pursued laboratory accreditation programs, adoption of such programs by commercial laboratories varies widely. The International Organization for Standardization (ISO) 17025 standard has

been used since 1999 as a basis for the accreditation of testing and calibration laboratories, including food-testing laboratories. ISO 17025 provides a framework upon which laboratories can build quality management systems to ensure data reliability. An ISO 17025 standard interpretation aid, issued by the Association of Analytical Communities International Analytical Laboratory Accreditation Criteria Committee (1), has served as an important tool for laboratories seeking accreditation, as well as for accrediting bodies to assure compliance and competency. While several local, state, and federal government laboratories have sought and achieved ISO 17025 accreditation, the population of commercial laboratories with ISO 17025 accreditation is relatively small. Increasing awareness of the importance of reliable data in supporting food safety programs has placed a spotlight on both laboratory competence and the use of validated, “fit for purpose” testing methods. Accordingly, food manufacturers and regulatory agencies are expressing competency and method expectations beyond those included in the ISO 17025 standard. However, such expectations are expressed with variable levels, based on whether the analysis is conducted on a commercial, third-party basis, or for regulatory purposes. Moreover, expectations that laboratory analysis is conducted according to ISO 17025 or analogous standards (such as those stated in the current Global Food Safety Initiative guidance) may lead to variations in the interpretation of equivalency. As expectations continue to evolve, guidance for establishing standards beyond ISO 17025 is warranted. This approach is needed to ensure laboratory competency and method performance, which in turn, will drive the generation of reliable data used to manage food safety programs worldwide.

The laboratory accreditation program, included as part of FSMA, is intended for laboratories that conduct regulatory testing on behalf of FDA, but may also include private laboratories. It is possible that the FSMA-directed accreditation program will encompass much of the ISO 17025 standard, although it is unclear at this time as to whether such an accreditation will sufficiently address FDA expectations. The relevance of laboratory accreditation per FSMA for private laboratories and non-regulatory food testing is currently unknown, as is whether expectations could potentially evolve into something similar to those for the pharmaceutical industry in that laboratory analysis is considered part of current Good Manufacturing Practices and thereby under the legal authority of FDA.

By comparison, non-regulatory testing for food items regulated by the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS), including meat, poultry, and processed egg products, also is conducted by commercial in-company or third-party laboratories without regulatory oversight. However, FSIS has recently issued guidance documents for regulated establishments to assist in the selection criteria for private laboratories, based on accreditation, technical competence, and validity of test methods. A recently updated guidance entitled “Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory,” is intended to provide free, easy-to-interpret information, including a laboratory assessment checklist for food processors to determine if the

laboratory, and associated data, are reliable (3). This guidance document highlights that FSIS laboratories are ISO 17025 accredited and that ISO 17025-accredited laboratories would meet their recommended guidance. The document also states that while laboratory accreditation is not a specific requirement, accreditation provides an increased level of confidence in the accuracy and quality of test results.

Laboratory accreditation per FSMA: Expanding FDA’s ability to test food, with quality and reliability

Section 202(a) of FSMA requires FDA to establish a testing program that uses accredited laboratories to augment the thirteen field laboratories currently operated by the agency and to utilize them to analyze samples in an effort to protect public health. The stated goal of Section 202(a) is to increase the number of laboratories that are qualified to perform testing of food. By expanding both the domestic and foreign capacity of food testing via accredited laboratories, an increased level of testing for routine surveillance, importing compliance, and foodborne illness investigations can exist. Additionally, the accreditation requirements are aimed to advance quality assurance and scientifically sound sampling programs, thereby driving the collection of reliable data more effectively. Quality is further enhanced by a grant program, under Section 210, which is designed to improve the capacity of laboratories to detect disease agents. Meanwhile, reliability is assured through direct reporting of test results to FDA, along with FDA review and periodic re-evaluation of accrediting bodies, and oversight of the laboratories they accredit, as described below.

Process of laboratory accreditation per FSMA

Under the program, FDA recognizes third-party, accrediting bodies that will accredit government and private laboratories to test food for regulatory purposes. These accredited labs will report results of public health concern directly to FDA. The agency is required to establish a registry of accrediting bodies and accredited laboratories that includes laboratory contact information. The accrediting body or the accredited laboratory is responsible for reporting any changes that would affect the recognition of the accrediting body or the accreditation of the laboratory.

What laboratories qualify for accreditation per FSMA?

Accredited laboratories may be government-operated or privately run. The only eligibility requirement is a demonstrated capability to conduct one or more sampling and analytical testing methodologies for food. Overseas laboratories also can be accredited, provided they meet the same standards applicable to laboratories located in the U.S.

Laboratories must be accredited for the particular sampling or analytical testing methodologies they use for analysis conducted for regulatory purposes. The scope of accreditation could be noted on the registry, enabling businesses to identify whether the laboratory is appropriate for the testing they are seeking.

An exception to this limitation is provided in cases where a new methodology has been developed and verified, but the laboratory has not yet been accredited to perform it, but only if the use of the new methodology is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak. This

approach ensures that the most advanced testing methodologies are available when needed, even if the accreditation process has yet to catch up with the advancement in methodologies.

Program expectations and accountability reviews

FDA is required to develop model sampling techniques and analyzing standards that an accredited laboratory must follow. The standards must include methods to ensure that appropriate sampling, analytical procedures, and commercially available techniques are followed. Reports of analyses must be certified as true and accurate. Other standards will ensure use of internal quality systems, procedures to evaluate and respond promptly to complaints regarding analyses, and employment of qualified personnel to perform the sampling and analysis. In addition to these specific requirements, FDA may establish other criteria.

To ensure the system remains accountable, FDA must review whether an accrediting body meets the requirements for recognition, no less than once every five years. The accreditation review may require that agency personnel accompany auditors from the accrediting body to assess whether or not the laboratory meets the criteria for recognition.

The agency is required to revoke its status if an accrediting body does not comply with FDA-mandated criteria. This approach may also result in laboratories losing their accreditation status as well. FDA is to specify terms and conditions that would allow an accredited laboratory to continue to perform testing under these circumstances.

FSMA-regulated food testing

Six months after establishing the accreditation program, food testing conducted for regulatory purposes (e.g., routine surveillance, importation, and foodborne illness outbreak investigation), must be performed by an accredited laboratory that is listed on FDA’s registry.

Circumstances when testing must be done by an accredited laboratory are when testing is conducted:

1. By or on behalf of the food’s owner or consignee in response to a specific testing requirement under the Food, Drug, and Cosmetic Act or its implementing regulations, or as required by FDA, when applied to address an identified or suspected food safety problem; and,
2. On behalf of the food’s owner or consignee in support of admission of an imported article of food, or as part of consecutive testing to resolve an import alert.

FDA has not issued proposed regulations on FSMA’s laboratory accreditation provisions; thus, it is unclear as to whether accredited in-company laboratories and/or third-party laboratories hired by a company, will be eligible to conduct such testing.

Reporting of results and other FSMA provisions

FSMA requires the accredited laboratory to send test results directly to FDA. The agency can waive this requirement if it determines the results do not contribute to the protection of public health. This requirement keeps the reporting system

TABLE 1. Location of laboratory accreditation provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S. Code

Description	Location		
	FSMA	FDCA	U.S. CODE
Domestic Capacity Building	§ 110		21 U.S.C. § 2204
Initial Report Describing Laboratory Networks	§ 110(a)(1)(E)		21 U.S.C. § 2204(a)(1)(E)
Report on Laboratory Capability, Progress toward Accreditation	§ 110(c)		21 U.S.C. § 2204(c)
Laboratory Accreditation	§ 202(a)		
Recognition of Accreditation and Program Requirements		§ 422(a)	21 U.S.C. § 350k(a)
Testing Procedures and Reporting		§ 422(b)	21 U.S.C. § 350k(b)
Food Emergency Response Network	§ 202(b)		21 U.S.C. § 2221
Grants to Build Laboratory Capacity	§ 210	§ 1009(a)(3)	21 U.S.C. § 399(a)(3).
Mutual Recognition of Foreign Laboratory Methods and Testing	§ 305(c)(6)		

from being overwhelmed with test results that fail to call attention to real or potential food safety problems. The waiver must be issued through regulations, suggesting this authority is not meant to be a case-by-case waiver.

FSMA does include a specific requirement for FDA to review testing by accredited state or local government laboratories if the results led the state to order a food recall. The review would be for the purpose to determine whether a national recall is warranted, or if FDA needs to take other compliance or enforcement actions.

Food emergency response network

While not a part of the accreditation program, Section 202(b) of FSMA requires FDA to report biennially on the implementation of a Food Emergency Response Network. This network is intended to provide surveillance, rapid detection, and surge capacity in cases of a bioterrorism attack on the food supply or other large-scale food-related emergency.

Final issuance of the rule

FSMA set a deadline of Jan. 4, 2013, for establishing the accreditation program with a requirement to use accredited laboratories, beginning six months later. FDA missed the statutory deadline. Presently, it is unclear when the program will start.

What does this rule mean for consumers?

Testing doesn't make food safe; food safety programs, processes, and associated verifications drive quality and safety of food production. Verifications often include testing; but finished product pathogen testing is rarely a meaningful avenue of verification. This discrepancy may be due to the inadequacy

of population sampling, as it relates to a very low incidence of the defect (i.e., pathogen) meant to be detected.

FSMA has given FDA more tools to regulate the foods under FDA's purview, making the agency more robust. It is anticipated that this approach will lead to fewer outbreaks, illnesses, and deaths attributable to foodborne pathogens in the U.S. Having the ability to establish, implement and oversee laboratory accreditation guidelines, as well as broaden domestic and foreign laboratory capacity, will support more efficient production of reliable data, and therefore, support FDA's efforts to protect public health.

What does this mean for food safety professionals?

Placing greater emphasis on laboratory expectations, including third-party accreditation, quality programs, technical competence, and use of validated methods allows for more clarity, and thereby, improved consistency across the industry in producing reliable data. Since FSMA currently applies to regulatory testing, commercial labs may or may not choose to implement such practices on all testing conducted at the facility, since testing would still be voluntary. Ideally, companies performing and/or requesting food testing to support important decisions about their process and products, including compliance with regulatory and global quality standards, demonstrate the value of providing specific laboratory expectations and for laboratory accreditation across the industry.

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About the Authors



Vanessa Coffman
is Education Manager
at STOP Foodborne Illness.



David W. Plunkett, JD, JM
is Senior Staff Attorney for the
Food Safety Program at the Center
for Science in the Public Interest.



George Wilson
is the Director of Business
Development & Marketing
for Invisible Sentinel.



Wendy Warren, Ph.D.
is Vice President of Government &
Regulatory Affairs at AEGIS Food
Testing Laboratories, Inc.