

Ensuring Food Safety



Through Accredited Third-Party Conformity Assessment

An ANSI-ASQ National Accreditation Board White Paper



Executive Summary

According to a February 2007 Government Accountability Office (GAO) report, each year approximately 76 million people in the United States contract a food borne illness, 325,000 require hospitalization, and 5,000 die. While, the United States benefits from a plentiful supply of food that is generally safe, federal oversight of food safety is fragmented, with no less than 15 agencies collectively administering at least 30 laws related to food safety.

The GAO observation that accreditation of private laboratories “could leverage outside resources while providing FDA greater assurance about the quality of the laboratories importers use to demonstrate that their products are safe” raises the question of whether the U.S. government alone can effectively and efficiently protect the nation’s food supply. In light of recent food safety-related incidents, the U.S. government – mainly Congress – is also asking whether private industry can effectively and efficiently protect the nation’s food supply.

Private industry must take a proactive approach and work in partnership with the U.S. government to ensure food safety. The nation’s domestic and imported food supply is too immense to be handled by the U.S. government alone. To ensure food safety and protect the populace, it is vital that government and private industry work together.

This is one reason FDA has implemented a Food Protection Plan with a strategy of prevention, intervention, and response. The plan would have FDA work with private industry. Specifically, FDA has embraced the concept of third-party conformity assessment to address food safety.

To have a truly effective food safety system in the United States, we must have a level of oversight that works in partnership with U.S. regulators to provide confidence in the entire life cycle of the product. This is best achieved through accredited third-party



conformity assessment services, by which an independent party verifies and provides written assurance of conformance to internationally recognized standards. The third-party verifier is in turn subject to assessments by an accreditation body to ensure it is competent to carry out its specific work. Third-party conformity assessment providers include laboratories, inspection bodies, management systems certification bodies, product certification bodies, and personnel certification bodies – all of which can be accredited by appropriate bodies to provide an added level of oversight and assurance.

Bills currently referred to the Committee on Energy and Commerce envision the use of accredited third-party conformity assessment programs, including but not limited to the use of laboratories accredited by FDA-recognized accreditation bodies. Beyond this, there is a role for the use of food safety management system standards, product certification standards, and relevant personnel certification. Because food safety is a global problem, Congress and regulatory agencies should use the existing recognition infrastructure for accreditation bodies established internationally through the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF).

Accredited third-party conformity assessment is a proven tool that will allow industry and government to effectively and efficiently protect the nation’s food supply. It is founded on international standards that establish clear requirements. It focuses on building and operating well defined and repeatable processes, ensuring accurate and reliable test results, establishing controls to monitor to ensure desired results, and the necessity for continual improvement. It is the goal of the ANSI-ASQ National Accreditation Board to promote this successful model in the United States to industry, regulators, and Congress.

Government-Industry Cooperation

To effectively and efficiently protect the nation's food supply, private industry must take a proactive approach and work in partnership with the U.S. government to ensure food safety. The growth of international trade has fueled a desire for use of international process and system standards written by standards-developing bodies in coordination with the industries by which the standards are used. The United States should use international standards where they exist, rather than relying on national standards or laws specific to a single market. The U.S. Department of Agriculture primarily operates under national statutes created in 1906, an untenable situation that in the 21st century begs the question: When will the United States finally modernize its food safety system?

FDA's New Food Safety Approach

FDA has announced that it is time for a new approach to food safety, and the agency is moving toward a proactive rather than reactive approach. With creation of the Food Protection Plan, FDA aims to integrate food safety and food defense. The three major elements of the Food Protection Plan are (1) prevention: building in safety from the start; (2) intervention: risk-based inspections and testing; and (3) response: rapid reaction and effective communication.

Prevention is primarily the role of industry. Industry's adoption of HACCP as a preventive action measure and regulators' subsequent endorsement of its use is commendable. However, the HACCP program has been undermined by industry and regulators. Organizations have kept two sets of books or used other means to hide important features of a HACCP or food safety plan so that regulatory bodies would not inspect or would not have the authority to inspect parts of the organizations' food safety systems.

Under the Food Protection Plan and in response to the undermining of the HACCP program, FDA aims to promote increased corporate responsibility, identify

where food vulnerabilities may exist, and assess the risk and expand the use and understanding of effective measures to mitigate the risk.

Intervention is essentially what FDA can do to get ahead of the curve. Response deals with improving response time through improved traceability and communication with the public, industry, and other stakeholders.

The recently issued draft FDA "Guidance for Industry Submission of Laboratory Packages by Accredited Laboratories" concludes that "rigorous accreditation standards give us more confidence that accredited laboratories have the technical capability and trained personnel to perform the specific methods for which they are accredited. Our confidence in the accredited laboratories' abilities and, by extension, the laboratory packages which these accredited laboratories generate, is enhanced by the accreditation bodies' continuing oversight over these accredited laboratories and our plans to conduct, from time to time, on-site visits to accredited laboratories..."

The document also says, "Having accreditation bodies be signatories to the ILAC Mutual Recognition Arrangement would result in consistent standards among accrediting bodies and accredited laboratories regardless of where these are located. This would enable us to have the same confidence in results from an accredited laboratory in a foreign country as we would have in results from an accredited laboratory located in the United States."

The ANSI-ASQ National Accreditation Board supports FDA's endorsement of accredited laboratories.

Drivers

Third-party conformity assessment has been embraced by some areas of government, including the Environmental Protection Agency, Consumer Product Safety Commission, Department of Defense, and Department of Homeland Security. Why? Because it is an effective means to achieve confidence in safe and reliable products and services. Equally important, users pay the costs for these services, reducing the cost to government. In addition, third parties can often cross international borders more easily and in some cases when and where U.S. government cannot.

Clearly, in some areas it is essential to keep direct regulatory oversight of high-risk areas. But turning over less risky areas of oversight to accredited third-parties allows reallocation of government resources to oversight of higher risk areas. This concept is currently implemented for medical devices by Health Canada under the Canadian Medical Devices Conformity Assessment Scheme (CMDCAS). Canadian regulations require that medical devices be manufactured under a certified quality management system that meets the criteria of ISO 13485.

For medical devices to be licensed by Health Canada, Canada's third-party accreditation body, the Standards Council of Canada, accredits organizations that certify the managements systems of medical device manufacturers. Health Canada relies on third-party accreditation for oversight of lower-risk medical devices, while maintaining its oversight of high-risk medical devices.

Food Safety Legislation

At the same time Congress appears willing to modernize the U.S. food safety system – in part because of competitive influences in the marketplace, industry is demanding a robust food safety management system that would benefit the entire supply chain. Organizations that rely on internationally accepted accredited third-party conformity assessment standards are well positioned in the marketplace because of the added confidence that conformance with standards can provide to consumers.

Committees of both the House and Senate are considering several proposals with regard to food safety and FDA, suggesting that new food safety legislation will be enacted in late 2009 or early 2010. The ANSI-ASQ National Accreditation Board supports bills under consideration that envision the use of accredited third-party conformity assessment programs, including use of laboratories accredited by FDA-recognized accreditation bodies. Because food safety is a global concern, there is every reason to use the existing recognition infrastructure for accreditation bodies established through the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF).

FDA should participate as a stakeholder member of

ILAC and IAF and use their evaluation processes, which encompass more than 60 accreditation bodies operating around the world. FDA could then report to Congress as necessary regarding its participation. By shifting the cost of evaluation by accreditation bodies to testing laboratories and conformity assessment (certification) bodies, FDA could dedicate more resources to improved surveillance, laboratory capacity and response, and potential product recalls to prevent and control food borne illness.

Accredited Third-Party Conformity Assessment

How do you standardize within the supply chain when standards are being developed by private industry, at the state level, by the federal government, and internationally? The answer is by testing, inspecting, certifying, and conducting accredited third-party conformity assessments. A number of approaches within the supply chain are possible.

In the first-party approach, known as self declaration, essentially the organization declares, “I meet the standards and I am ok.” This can be a viable approach to the degree that you trust the organization – because the organization's own declaration is the only assurance provided.

In the second-party approach, an organization in the supply chain is contractually obligated to make sure it meets specific customer requirements and the customer (or second-party) may conduct its own tests, inspections, or audits of the first party. An OEM or key provider may “certify” as much as it can, typically at the very top level of the supply chain, leaving out everyone else below.

The accredited third-party approach has oversight to provide checks and balances across the spectrum of services provided. This is the only way to ensure the entire product supply chain conforms to standards.

Some third-party organizations are not accredited by globally-recognized bodies and operate according to internally managed controls rather than international requirements. Known as third parties without oversight, these organizations in some cases conduct inspections or certification audits at a fixed point in time and/or to processes they have established,

rather than relying on recognized standards. As a result, they operate with little or no accountability and questionable impartiality. Historically, third parties without oversight represent a problematic approach, a recent example of which is the situation with the Peanut Corporation of America.

With accredited third-party programs, by contrast, oversight is in place to prevent inappropriate practices. When third-party conformity assessment organizations are accredited by ILAC-and IAF-member accreditation bodies, an added level of oversight provides greater assurance of the soundness and credibility of their work.

Using the third-party approach and requiring that each link of the supply chain operate according to international standards ensures that all are playing by the same rules. International standards form the foundation on which the entire process is built, and additional requirements can be added to this foundation as appropriate. ISO 22000, the international food safety management system standard, could be used throughout the food supply chain, with additional standards coming into play for labs, product certification, or personnel certification. This would eliminate the problem of one OEM dictating its own standard and another dictating a different standard or requirement, when a single international standard could better serve everyone. By relying on international standards and the ILAC-IAF recognition process, FDA, Congress and industry can be assured of consistent application of the accreditation process.

ISO 22000 Food Safety Management Systems

The ANSI-ASQ National Accreditation Board supports the use of ISO 22000 as a preventive action tool as a means to meet the goals of the Food Protection Plan. ISO 22000 is essentially Codex HACCP within an international management system standard. The standard can be very effective in addressing food safety concerns if industry and regulators embrace its use and do not undermine it.

ISO 22000's emphasis on the safety of the production process and the product helps the organization focus its energies on developing and maintaining a strong



functional food safety management system. The standard addresses requirements needed for prerequisite programs and development and maintenance of a HACCP plan. It explains in detail the preliminary steps to enable the hazard analysis, requirements of the hazard analysis, establishment of the HACCP plan, and verification and validation of the effectiveness of the plan. Because of its integration with HACCP Codex – the most recognized and accepted food safety standards in the world – ISO 22000 is an obvious choice for an industry-wide standard.

ISO 22000 implements disciplines that have worked successfully within other ISO standards and applies them to food safety. The components of the standard are vital in the development and maintenance of a food safety management system, and the standard defines management commitment and responsibilities throughout the entire organization.

While ISO 22000 is not as detailed or prescriptive as other standards, it can fit into any existing food safety plan. It is compatible with any existing system, including any additional requirements, and will enhance the effectiveness of that system.

It is up to the individual organization to identify the prerequisite programs required. ISO 22000 requires the organization to satisfy any regulatory requirements instead of specifically laying out requirements for building and equipment design and construction. This prevents the standard from becoming lengthy and unmanageable, and ensures that it is broadly relevant in the food industry. Organizations identify the hazards specific to their situations so they can develop plans to control them. ISO 22000 essentially becomes a living document for the organization.

Disciplines similar to those required for other standards are required by ISO 22000. ISO 22000 aligns well with other ISO standards but addresses a specific need: food safety. Because of this alignment with other ISO standards, such as ISO/IEC Guide 65 for product certifiers and ISO/IEC 17025 for laboratories,



Laboratory Accreditation to ISO/IEC 17025

It is vital that industry and government have the confidence of the public with regard to food safety and accreditation of laboratories is a crucial element in providing public confidence. Confidence in imported and domestic food is enhanced when the public knows all steps have been taken to ensure that food is of good quality, is safe, and will not harm them.

With confidence in the data used to establish baselines for key analyses and decisions, uncertainties associated with decision-making can be minimized. This is critically important when decisions affect the safety or quality of food, human health, and the environment. Use of accredited laboratories in the food industry reduces uncertainty for good decision making.

No matter how good a system is maintained under management system standards, the system can result in a tainted product if the product is not tested by a competent laboratory or, worse, not tested at all. A failing of the food industry is the lack of widespread accreditation of commercial and internal labs to international standards such as ISO/IEC 17025. Accreditation provides assurance that the lab is producing accurate and reliable test data, minimizing the risk associated with bad product. Accreditation provides the customer confidence in test results, precluding the need for independent verification. Where independent lab accreditation is necessary, using internationally agreed criteria is an effective means of ensuring competence and trust.

Why Lab Accreditation?

Because the most important responsibility of government is to protect the health and safety of the public, regulations and laws relating to food safety are necessary. But when international standards overlap requirements for regulator oversight, there is an opportunity at a minimum to reduce the amount of time regulators spend on site. This is possible when trust in lab accreditation exists. There is too much redundancy in the current marketplace; this increases costs for the organization being audited, taxpayers, and consumers.

A laboratory accredited by a reputable third-party accreditation body has achieved a prescribed level of technical competence to perform specific types of testing, inspection, measurement, and calibration activities. Lab accreditation results in organizations capable of producing data that is accurate, traceable, reproducible, and cost effective; these are critical components for good decision making in government and industry.

Most important, by providing formal recognition to competent organizations, lab accreditation provides a conduit for regulators and industry to find reliable products and/or services able to meet their needs. One method for this is to share audit reports with the appropriate regulators.

It is vital to have the confidence of users, whether they are in industry, government, or the consuming public. Testing labs can play a crucial role in the product life cycle of food, but users must be confident in the results coming from the test data. Accreditation is the means to provide the needed credibility.

Lab accreditation is also a factor in controlling costs. If testing of products is not done correctly, the cost and time involved in re-testing is even higher than when a product fails to meet expectations or specifications. Associated costs may include negative consequences for the reputation of the supplier or manufacturer and liability in the event of a product failure, especially if it involves public safety or financial losses for customers. By ensuring the technical competence of a lab, accreditation provides assurance that products produced or purchased meet expectations and/or conform to specific requirements, minimizing the risk of producing or supplying a faulty product.

Lab Accreditation and International Trade

In addition to playing a vital role in ensuring public confidence, lab accreditation facilitates trade and economic growth. The World Trade Organization has identified the lack of acceptance of laboratory test data across national borders as a significant barrier to trade.

For most traded products, confirmation that they comply with specifications and safety regulations is required before they can be released to the market. Consumers may also want evidence that products are in compliance. Textiles, petroleum products, wine, and other commodities, as well as consumer products such as electronic goods and packaged foods, are traded almost entirely on the basis of technical specifications. Increasingly, the global economy demands accurate data and information on toxicity of drugs, safety of food additives, environmental pollution, and a host of other concerns. Lab accreditation ensures reliability of the test data used for making informed decisions on purchases and use of goods.

Lab Accreditation Oversight

A system of agreements – known as mutual recognition arrangements (MRAs) – allows mutual evaluation and acceptance of accreditation systems across national boundaries. These MRAs allow test data to be accepted between countries in lieu of having testing repeated in each country by each country's relevant interests. Instead, each partner to the MRA recognizes the other parties' accreditations – and activities conducted under those accreditations – as equivalent to their own.

Consider the fact that roughly 80% of seafood consumed in the United States is imported. Although FDA is improving its inspections of foreign organizations, its resources are limited. The GAO has recommended that FDA use both state and private laboratories to analyze imported food. Accredited third parties can be used to augment these FDA programs.

Because data generated by a laboratory that is accredited is more readily accepted in overseas markets, reliance on the international model of MRAs

will reduce costs and ease exports and imports, as it reduces or eliminates the need for re-testing. This is an effective means to assist U.S. regulators in their mission of protecting public health and safety.



Conclusion

Some in Congress, among regulators, and in private industry do not yet accept international standards and accredited third-party conformity assessment programs, and specifically have not fully embraced accreditation of labs and accredited certification to food safety management systems. But the potential benefits of implementation of international standards such as ISO 22000 and ISO/IEC 17025 within the food industry far exceed any potential negatives in requiring them as a part of any U.S. food safety legislation.

Accredited third-party conformity assessment is a proven tool that will allow industry and government to effectively and efficiently protect the nation's food supply. It is founded on international standards that establish clear requirements. It focuses on building and operating well defined and repeatable processes, ensuring accurate and reliable test results, establishing controls to monitor and ensure desired results, and the necessity for continual improvement.

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