

Introductory Comments

The American Council of Independent Laboratories (ACIL) was founded in 1937 as a national trade association representing independent third party scientific laboratories, testing, product-certifying, and R&D firms as well as consultants and suppliers to the industry. ACIL defines an independent third party testing firm as a commercial entity engaged in public services and consulting including analysis, testing, inspection, materials engineering, sampling, product certifying, research or development, and related activities. An ACIL independent third party laboratory is not affiliated with any institution, company or trade group that might affect its ability to conduct independent investigations, render reliable reports, or provide professional scientific advice objectively and without bias. ACIL's 150 member companies operate approximately 1,500 facilities across the U.S. and abroad. They range from the one-person specialty laboratories to multi-disciplined, international corporations employing thousands of analysts, risk management specialists, consultants, and support staff. American consumers are already relying on the efficient and reliable scientific resources of ACIL member labs, which together with manufacturers and importers ensure the safety of imported foods, cosmetics, pharmaceuticals, and ingredients on a daily basis.

One of ACIL's sections is Food Sciences (FSS), which focuses on laboratories offering microbiology and analytical chemistry services for the purpose of characterizing composition, purity, residue, content, and contamination in the food, pharmaceuticals, cosmetics, and related product manufacturing industries.

ACIL and the FSS committee commented on the Food Safety and Modernization Act (FSMA) of 2010. Given the critical roles ACIL/FSS members have played for many years in the FDA regulation of food and related imports, ACIL members are uniquely qualified to provide advice on the scientific and operational considerations FDA should consider in their implementation of FSMA

For many years ACIL members have worked cooperatively with the manufacturing and importing industries and FDA by providing necessary and reliable inspection and analytical services, the outcome of which ensure the safety and compliance of imported FDA-regulated products.

ACIL has advocated for years the FDA establish uniform requirements for private laboratory submissions and that it seek improved consistency in analytical data to allow it to make better and more efficient food admissibility decisions. ACIL members also believe it critical the FDA establish uniform standards among its District offices and laboratories in their review of private laboratory submissions. Ensuring integrity in this process will directly benefit ACIL's members, the FDA, and most importantly the consumers who rely upon our combined efforts. Further, ACIL has consistently and repeatedly urged FDA to adopt and recognize International Standards Organization (ISO) accreditation as the primary basis for qualification of laboratories to submit analytical data to FDA for any purpose. We are pleased that FSMA addressed these issues and look forward to working with FDA on their implementation.

Overview Comments

ACIL believes FSMA represents a significant step forward in implementing a more risk-based import program. Further, once implemented, the Act will serve to expedite the importation of perishable food products while maintaining confidence that those products are safe, wholesome, and unadulterated. ACIL expects that through the implementation of the Act, FDA will expend fewer resources reviewing laboratory packages while maintaining a high level of confidence in the safety of the products being imported. This, in turn will enable FDA to focus its limited inspection, sampling, and laboratory resources on higher risk shipments and in investigating new threats to public health and analytical methodologies to deal with them.

ACIL also expects that with standardization between FDA and independent third party laboratories and samplers, the FDA will be able to utilize accredited private labs to perform sampling and testing under its Surveillance programs. This would allow a substantial increase in the number and percentage of import shipments to be examined prior to their entry into the USA, and thereby provide proportionately greater assurance that imports meet FDA standards in the public interest. In recent years, the FDA has examined a progressively smaller percentage of food and related imports, and this would allow the agency to reverse this trend.

ACIL notes that FDA has not established consistent standards for product sampling of imports. Although some FDA districts have

implemented local policies, there remain inconsistencies the FDA must address including such issues as the required qualifications, training, viewing and photographing shipments, precautions required to assure sample integrity until it reaches the laboratory, and so forth. ACIL welcomes the opportunity to work with FDA, NACLA and accrediting bodies to develop such standards that can then be assessed by accrediting bodies to ensure FDA requirements are met.

ACIL further believes all sampling for analysis by a private laboratory should be performed by independent third party samplers – either by laboratory personnel or professional independent samplers – and not by the importer of record, or owner of the product to be tested, or by unqualified warehouse personnel. Any other approach critically compromises the integrity of the sample and the test data.

The ACIL welcomes the opportunity to work with the FDA, the accrediting bodies, and the private laboratory industry to jointly develop standards that can be assessed by accrediting bodies to ensure FDAs requirements in assuring food and related imports meet its standards are met.

What Does "Accreditation" Mean?

For purposes of this document, accreditation refers to a rigorous assessment, conducted by an independent science-based organization, to ensure the overall capability and competency of a laboratory and its Quality Management Systems comply with a specified set of guidelines (e.g., ISO 17025:2005). An accredited laboratory should have established standard operating procedures that are routinely followed and have quality systems in place for identifying and correcting deviations from those procedures. The independent organizations that accredit laboratories are known as "accreditation bodies."

We recommend that private laboratories be accredited for the specific test method(s) that they use to generate the data and test results they submit to FDA. That is, in addition to a general assessment of the private laboratory's operations, we are recommending that an accreditation body assess the specific sampling techniques and analytical capabilities of the laboratory, including equipment and personnel, which the laboratory uses to generate the data and prepare the report that it submits to FDA. A laboratory might be accredited for one method and not for another. Accreditation would indicate that the private laboratory is competent to perform a specific test method(s) within the scope of its accreditation.

Model Lab Standards for testing and sampling

ACIL agrees with previous FDA's statements that the Agency's Import Alerts should reference the methods, and sampling plans used to identify the violations charged in the Import Alerts. These methods and sampling plans will then be used as the basis for presentation of evidence to FDA for importers seeking to overcome the appearance of an FDCA violation

Sampling

An accredited laboratory is responsible for ensuring the integrity of the sample it analyzes and that the sample is representative of the lot being tested. Either the accredited laboratory should collect the sample itself or the accredited laboratory can subcontract with an qualified independent third party to collect the sample in accordance with the accredited laboratory's accreditation.

Appropriate sampling protocols should ensure that sample integrity is maintained from the time of collection until the sample is delivered to the laboratory. Sampling should be conducted in accordance with the sampling procedure cited in the Import Alert.

Identification of the sample should include the:

- U.S. Customs and Border Protection entry number;
- FDA entry line number, if applicable or available;
- Location where product was sampled (including warehouse or cold storage lot numbers if available), and
- Marks noted by the sample collector on the containers from which samples are collected.

The sample collection report should include information on the:

- Identity of the sample collecting entity, whether an accredited laboratory or a sampling service;
- Identity of the individual collecting the sample, whether employed by an accredited laboratory or a sampling service;
- Invoiced quantity that was made available for sample collection;
- Sample collection date;
- Sample collection method;

- Sample preparation techniques;
- Lot size and identification number;(if available)
- Production code (if available);
- Sample size
- Observations by the sample collector about the condition of the lot, containers or other conditions that could affect the sample's integrity.

The person collecting the sample should ensure that original labels or labeling are collected and submitted along with the sample. If that is not possible, pictures of the labels or labeling should be collected and submitted instead.

TEST METHODS

The stated "Test Method" prescribes the use of any method that is validated and fit for its intended application and for which the laboratory is accredited, or that FDA otherwise identifies as suitable is appropriate. We hope that any applicable Import Alert will reference the method that was used in identifying the violation for which an entry is detained. In the event that only one method has been developed for the relevant analysis, we expect that any Import Alert will identify the specific method or set out the analytical figures of merit associated with an appropriate method, including: linearity, accuracy, precision, limit of detection, limit of quantitation, selectivity, stability in matrix, process sample, stability, robustness, sensitivity, and reproducibility.

Accredited laboratories can use methods different from those identified by the agency, provided that it uses validated methods, which will ensure method performance criteria are met, including sensitivity, as outlined in the previous paragraph.

New Methodologies

ACIL members agree that, in general, accreditation must be required for the specific analysis an accredited laboratory performs for submission to FDA. Accreditation of a laboratory for other unrelated analyses is not an adequate criterion to ensure the quality of private laboratory submissions. However, in order to ensure flexibility in the use of private laboratories, the FDA will need to accept some private laboratory submissions where the laboratory is accredited not for the specific analytical procedure, but rather for related procedures employing similar technology. There are thousands of method/analyte combinations, and it is impossible to expect private laboratories to be accredited for them all.

Further, the agency will be expanding its testing capabilities in evaluating new or previously unidentified analytes of concern in complex food, cosmetic, drug, device and biologic matrices. As a result, the FDA will be developing new methods private laboratories will be asked to perform. No private laboratories will have been previously accredited for them. ACIL recognizes that FDA is not likely to permit accredited laboratories which are not accredited for the new methods to enjoy the same level of confidence they enjoy for more established testing methods, but we do believe that there is value in laboratory accreditation alone, which could be extended here.

The ACIL recommends, for newly developed test methods, all accredited private laboratories would be expected to present a laboratory package, including the raw test data, to FDA for review. If, however, an accredited private laboratory is also accredited for the technology used in the new methods, this should be considered by FDA field laboratories as a basis for conducting only a simplified review of the analytical results.

ACIL believes this recommendation represents a reasonable and scientifically valid compromise that allows for the use of third party laboratories in these events. In addition, even if FDA has confidence in a particular laboratory's ability to implement new methods, there is value in FDA obtaining the raw data related to new test methods so the agency can determine appropriate modifications and revisions to the methods. ACIL believes this will be particularly important for many of the new methods FDA or others will develop, as they will increase with new and emerging scientific and product safety concerns.

Recognition of Accreditation Bodies (ABs)

Public Law 111 – 353, The *FDA Food Safety Modernization Act (FSMA)*, Title II, Sec. 422, focuses on one of the most critical segments of the foundation of this law. The recognition of accreditation bodies (ABs) is the function that forms the basis of the new safety net being established by FDA to provide for the security of the US food supply. The strongest possible framework for developing a system for recognition of accreditation bodies involves the FDA, as well as various ABs, laboratories and other interested parties.

This vertically integrated structure already functions smoothly for a number of government agencies using the NACLA model, and NACLA is convinced that this vertically-integrated decision-making model is the proper foundation that should be used by FDA. This vertical structure,

which would involve the solicitation of knowledgeable input from all affected parties and making that information readily available to the FDA, is the best model that can be used to implement FSMA requirements.

Located in Washington, DC, NACLA is a not-for-profit corporation established in 1998. It was founded by representatives of public and private-sector organizations to provide coordination and focus for laboratory accreditation programs in the U.S. NACLA's primary mission is to evaluate U.S. laboratory accreditation bodies (ABs) and to grant recognition to ABs found to be in compliance with NACLA procedures and the relevant international standards for competent ABs. (Note: NACLA does not itself accredit laboratories.) NACLA also provides educational and training opportunities to persons interested in laboratory accreditation.

NACLA is a stakeholder organization. Accordingly, its leadership body (the Board of Directors/Operations Council) is comprised of balanced representation from the four key stakeholder groups: Industry, Government, Laboratories and Accreditation Bodies. NACLA's stakeholders work toward one common goal -- the standardization of laboratory accreditations throughout industry.

In most economies, there is a single national or government controlled accreditation body responsible for the assessment and accreditation of all laboratories. The United States is one of the few economies that privatized this function; therefore, many for-profit accreditation bodies operate in the United States. It is essential that these accreditation bodies are evaluated to ensure the accreditations awarded to laboratories providing testing and calibration services to U.S. customers are consistent in their interpretation of national and international standards, as well as application of technical rigor.

In addition, regulators and specifiers from government and industry need to ensure that their individual needs are being met by the accreditation community. This mandate includes ensuring that sector specific requirements are appropriately incorporated into the assessments of laboratories providing testing and calibration services to these government and industry customers.

NACLA is unique in that it is the only recognition organization in which government regulators (Federal Highway Administration, the U.S. Navy, etc.) and industry specifiers (automakers, the airline industry, etc.) play an active role in the formulation of evaluation criteria including recognition, review, and approval of accreditation bodies.

The laboratory group of stakeholders in NACLA is represented by the American Council of Independent Laboratories (ACIL). ACIL and NACLA have a Memorandum of Understanding (MOU) to ensure that technical rigor is maintained in the sector-specific technical requirements that will be demanded by a U.S. regulator. NACLA, in turn, develops evaluation criteria for these requirements and includes these criteria in its evaluation of accreditation bodies for recognition. NACLA-recognized accreditation bodies then perform site assessments, which include these sector-specific requirements. Through this process, NACLA provides confidence to government and industry that their particular testing and calibration requirements are being uniformly applied and achieved, while avoiding the cost of multiple laboratory audits.

NACLA provides training for specifiers and regulators to enhance the understanding of standards and improve compliance with those standards by agency personnel. Training also is available to help improve understanding and compliance by those complying with the standards.

Therefore, ACIL recommends that Signatories to NACLA also maintain conformity to the current version of ISO/IEC 17011. Accreditation body participation in NACLA ensures that that sector-specific technical requirements (in this case FDA technical requirements) are met by allowing FDA representatives to participate in on-going recognition and technical committee meetings in the United States as well as participate in accreditation and recognition assessments when necessary.

Lab Accreditation

ACIL agrees that private laboratories should provide to FDA, for its review, the results of their audits and notifications if accreditation is withdrawn. Further, ACIL agrees that private laboratories should send reference-specific methods used in testing product, the results of which are to be submitted to FDA.

Insofar as FDA in working with NACLA and the AB's will specify its requirements for accreditation, and conformance to these requirements will be audited by AB's, the FDA should be able to review the results of private laboratory submissions, and not routinely examine supporting documentation as it does now. This will expedite the release or refusal of imports and save the Agency significant staff time that can be then allocated to other purposes.

Procedure for resolving disputes between the FDA and private laboratories and sampling services.

ACIL members have also reported difficulty with disparate documentation requirements imposed by different FDA laboratories for demonstrating the proficiency of an analyst performing analyses for obtaining release of DWPE articles. These difficulties have, on rare occasion, risen to the level of a dispute between the laboratory and the FDA field offices. When seeking clarifying guidance from FDA headquarters (DFS and DIOP), ACIL members have experienced long delays when requesting a hearing on the questions involved. The FDA must establish procedures whereby private laboratories may appeal FDA District decisions very quickly and efficiently. As part of laboratory accreditation, the FDA must provide private laboratories and sampling services "due process" to ensure that FDA cannot disqualify a private laboratory from performing import testing services without a fair hearing. The existing situation places private laboratories at an untenable professional liability risk.

The FDA must establish a continuing Agency/private laboratory working committee to assure proper communication between the private laboratory community and the FDA.

Sampling and testing upon arrival is essential to the integrity of the DWPE process

ACIL respectfully submits that food shipments subject to Detention Without Physical Examination (DWPE) should be sampled only after presentation of import documents and while the goods are in the U.S. ACIL regards this limitation as essential to assuring the sample is representative of the actual shipment that is presented for entry into the U.S. This protection prevents analysis of a sample that is not from the shipment actually presented for entry into the US or analysis of a sample taken prior to product adulteration.

It has been argued that using an accrediting body that is also a signatory to the ILAC Arrangement would enable FDA to rely on the data no matter where the lab was located. This would enable FDA 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 in the United States. ACIL concurs in this principle, but insists the location of the laboratory to perform analysis should not justify a decline in the integrity of sampling.

While the work of an accredited foreign laboratory may be of the same quality as a U.S. accredited laboratory, FDA would lack the assurance the laboratory results actually related to the shipment of product imported into the U.S. and for which the laboratory results were presented as *evidence* of compliance. The majority of cases in which private laboratory results are relevant are DWPE entries subject to FDA Import Alert. These suspect shipments warrant close scrutiny. Accordingly, DWPE sampling and analysis is intended to demonstrate that these suspect shipments are compliant with FDA requirements.

Therefore we recommend that for testing of merchandise offered for sale in the US that the sampling of the entry occur after presentation of documents and while the goods reside in the US. Once the sampling is accomplished any qualified accredited laboratory may perform the necessary analysis.

Expanded use should include FDA Surveillance Program sampling and analysis.

1. BACKGROUND

On January 29, 2008, the Government Accountability Office (GAO) testified before the House Subcommittee on Oversight and Investigations. The GAO's testimony recommended, among other things, that FDA "consider accrediting private laboratories to test seafood" (see GAO, "Federal Oversight of Food Safety – FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical," GAO-08-435T, at page 7). The GAO stated 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" (id.)

In early 1994, the National Coalition of Food Importing Associations (the "Coalition" or "NCFIA"), working in conjunction with FDA's New York District, conducted a private laboratory pilot test. That pilot test was limited to seafood and was conducted solely in the agency's New York District from April 18, 1994 through December 31, 1994. The pilot allowed seafood importers to use private laboratories, rather than the FDA's North East Regional Laboratory, for surveillance analysis. The objective of the 1994 pilot project was simple: to test an approach that might expedite the admission of FDA regulated imported food (i.e., seafood) while not compromising public health, or exposing the public to additional risk. By all accounts, the FDA's New York District, the National Fisheries Institute, and the participating seafood importers considered the 1994 private laboratory pilot test an overall

success.

2. OBJECTIVES OF THE SUGGESTED PILOT TEST

The FDA should initiate one or more new Pilot Programs utilizing private laboratories accredited to ISO-IEC 17025:2005/AOAC (food and beverages) and other laboratories that have a history of meeting FDA requirements as soon as possible.

The general objective of the suggested pilot test ("Pilot Test") is to evaluate the use of private independent laboratory testing, as an augmentation of FDA testing, for surveillance coverage of FDA regulated food entries. Specifically, FDA can expect that the Pilot Test will provide information on whether accredited private laboratory testing of imported foods will provide the same level of surveillance coverage and consumer protection as FDA testing of such foods. In addition, FDA can expect to gather information about whether the use of such laboratories would sufficiently decrease FDA expenditure of resources, without diminishing consumer protection, thereby making the development of a program utilizing accredited private laboratory testing for the surveillance of imported food products worthwhile. Based on the experience gained and data collected by FDA regarding the analyses performed by accredited private laboratories, FDA will gain confidence in their results. FDA can then evaluate whether the use of the private laboratories will facilitate expediting import traffic in the especially busy Ports of New York–New Jersey and the Ports of Long Beach–Los Angeles. Under this Pilot Test, FDA will continue to make all compliance decisions as well as the final determination of whether specific entries of imported food may be released into domestic commerce.

3. HOW THE PILOT TEST WILL WORK

- (a) Import entries must be made electronically on OASIS.
- (b) When FDA determines that a sample is needed for one or more line items in an entry, FDA intends to communicate to the Importer and its broker whether the entry may be voluntarily tested by a Participating Lab and what type of analysis is necessary. FDA plans to provide this notification of sampling through the usual channels (i.e., electronically, telephone, and hard copy notice).
- (c) If the Participating Importer decides to utilize the Pilot Test, it will be required to advise the New York District or Los Angeles District, as the case may be, electronically or by facsimile that the Participating Importer will have the samples collected by a third party sampler and tested by a Participating Lab, at the

Participating Importer's expense. Such notification will include certification that only one sample will be taken and all resultant analyses will be submitted. The Participating Importer or its broker must identify the third party sampler and the Participating Lab that will perform the testing. If the designated FDA district does not receive a written response from the importer or broker within two working days from the issuance of the Notice of Sampling, FDA plans to conduct sampling and testing in the usual manner.

- (d) Upon FDA receipt of the Participating Lab's results for an entry, FDA personnel will review the results with the intent to make a decision on whether to release or to audit sample the product, by the end of the next business day following receipt of the results.
- (e) FDA will notify the Participating Importer or its broker of its decision whether to release the product or to audit sample the product as soon as the decision is made.
- (f) Where FDA decides to conduct audit sampling, FDA intends to collect the samples within 48 hours of the notification sent to the Participating Importer or broker of that decision. After comparison of FDA's test results with the Participating Lab's test results, FDA may release the product, where appropriate.

Direct Submission of Results to FDA

Rigorous accreditation standards will give the agency more confidence that accredited laboratories have the technical capability and trained personnel to perform the specific methods for which they are accredited. FDA's 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. Therefore, we would suggest that abbreviated laboratory packages from accredited laboratories, when combined with the other recommendations in this document, can provide FDA with information and assurances comparable to those contained in full laboratory packages from non-accredited laboratories. We believe that the contents of an abbreviated laboratory package from an accredited laboratory would provide appropriate information on which to make an admissibility determination.

With greater assurance about the information submitted by accredited laboratories, the agency could review the abbreviated laboratory packages more quickly, and this will enable FDA to decide whether to

admit these products into the United States more quickly than if it had to review full laboratory packages. While full laboratory packages include the details of any analyses performed and raw data, the *abbreviated laboratory packages focus on the test results and could* take less time to review. As a result, products meeting FDA standards should move more quickly into United States commerce. FDA would also be able to reallocate its own laboratory and field resources to other purposes

Private laboratories submitting reports to the NY FDA District (Jamaica and Port Elizabeth only) currently send Detention Without Physical Examination (DWPE) Reports applicable to food imports electronically to a dedicated email address. The FDA Compliance Officer is notified by a separate email that the reports have been posted. The FDA then uses secure passwords and other information as may be required to access and print off the Report for their review. In some cases, the report may be too large to allow it to be sent as one email and is therefore sent as multiple, consecutive emails. ACIL supports this and believes it should apply to all FDA Districts and all DWPE reports.

In the San Pedro FDA District, Reports are also sent as email attachments but the private laboratory is required to send the written Report by courier for next day delivery to the District Office.

If the office is under the aegis of the Southeast Regional Lab, the original written reports must be sent to the Atlanta office and photo copies of the report are sent to the home office by overnight courier.

In other FDA Districts, the Agency currently does not accept DWPE Reports electronically. The ACIL believes this is wrong.

In all FDA Districts except New York, where Reports are sent as email attachments, the private laboratory is required to send the written Report by courier for next day delivery to the applicable Compliance Officer.

The FDA Compliance Officer may request review of private laboratory submissions by FDA analytical staff but at this time the private laboratory does not submit Reports to the FDA regional branch laboratories except in the Southeast district.

The FDA should allow or require the private laboratory to submit their DWPE Reports electronically to both the applicable Compliance Officer and reviewing FDA laboratory. This would allow an expedited review

and release procedure essential for the importers to comply with FDA regulations.

The FDA should also allow the chosen private laboratory access to FDA "due dates" as well as the Import Alert applicable to the specific import. This will assist the private laboratory in meeting FDA analytical and time requirements.

Currently the districts are not consistent with the way comments and or questions about laboratory packages are handled; in some districts there are just abbreviated comments and or refusals of packages communicated to the importer. This leads to confusion and a great deal of miscommunication.

ACIL suggests that all questions and or comments about the laboratory package whether from the lab reviewer or the compliance officer be sent directly to the laboratory for their response.

Including Accredited Independent Laboratories to Participate in the Food Emergency Response Network (FERN) and eLEXNET

ACIL believes accredited members should be allowed to participate in the FERN and eLEXNET networks. Accredited members using recognized national and international standards should be included in the preparation for managing a possible "surge" of samples caused by natural or other disastrous events. The large amount of scientific and technical expertise residing in the ACIL membership can contribute significantly to technology transfer, validation, and implementation of standard analytical methodologies. For example, FDA, USDA, ACIL, and other scientifically based analytical entities could collaboratively conduct training and seminars for international industry and domestic industries on methodologies and validation of the methodologies in various food matrices. Additionally, ACIL accredited laboratories, under a well defined scope of work, could support FDA's methods development and validation through collaboration with the agency. FDA could also leverage resources with accredited ACIL members to identify validated methods for minimal detectable levels of adulterants. These solutions would address real, existing needs within FDA's regulatory food science programs, for both domestic and imported foods.

Economic impact

We are aware that several of our comments as well as the overall implementation of the act will have economic consequences. We will undertake in a future submission to document what the economic consequences will be in regards to the above.

Sincerely,

A handwritten signature in black ink, appearing to be 'M. Bush', written in a cursive style.

Milton M. Bush, JD, CAE
Chief Executive Officer