Issued: June 2014

The Food Safety Modernization Act: The Role of In House Testing, 3rd Party Labs and Accreditation

The Acheson Group, LLC (TAG), led by Dr. David Acheson, is a strategic consulting firm for food and beverage companies and those providing technical support to the food industry. With a focus on strategic risk management, TAG provides the latest food safety consulting insights in a global environment in providing Operational Risk management, Reputational risk management, and Regulatory Risk services—all with the goal of achieving brand protection. TAG works with all supply chain segments, from farm to manufacturers, retail and food services providers – domestic and foreign – focused on providing first rate services in a cost- conscious environment.

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Background

Will FSMA require food companies to perform more testing?

Will companies have to use 3rd party accredited labs?

Will FDA have access to test results?

These questions are top-of-mind for many in the industry. FSMA is large and complex, and requires FDA to develop numerous rules. As drafts of many of these rules have been released, there has been confusion and questions regarding the role of testing in FSMA. There have also been additional questions around any in house testing, possible restrictions on the types of labs that can perform these tests, methods that can be used, confidentiality of results, etc.

Word on the Street…

The Acheson Group (TAG) has heard many questions related to this topic. In this paper we will address what FSMA says and doesn't say, how FDA may interpret their authority in certain areas, and what the future looks like in terms of testing from a regulatory perspective.

The bottom line is that while FSMA provides FDA with the authority to develop a program for the accreditation of laboratories, the requirement for the use of these laboratories is extremely limited. Food companies will *not* have to use FDA-accredited laboratories, or any 3rd party labs for that matter, for their routine testing needs. Companies that currently perform testing in-house can continue to do so: FDA is not going to stop or discourage you as long your laboratory is using validated methods and is capable of performing the tests.

…Frequently Asked Questions

- **FSMA contains a section on "accreditation of laboratories". What does this mean? Is this ISO 17025?**
- **Will the accreditation apply only to 3rd party labs, or in-house labs?**
- **When will the food industry be required to use these "accredited laboratories"?**
- **The currently proposed Produce Safety Rule contains some testing requirements. Will these require farms to use accredited laboratories?**
- **Will the final Preventive Control Rule require environmental or finished product testing?**

- **If the Preventive Control Rule requires testing, must that be done by an "accredited laboratory"?**
- **Do any sections of FSMA require that laboratory tests be performed by 3rd party laboratories? Is there any indication that in-house testing will be negatively impacted by FMSA rules?**
- **Will 3rd party labs be required to share test results with FDA?**

The Answers…

- **FSMA contains a section on "accreditation of laboratories". What does this mean? Is this ISO 17025?**
    - No, "accredited laboratories" as defined with FSMA are not ISO 17025 accredited laboratories, but would be accredited under an FDA program. Section 202 of FSMA (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC202) requires FDA to establish a program for the accreditation of laboratories. FMSA specifies that "The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and included in the registry provided for under paragraph (1). In developing the model standards, the Secretary shall consult existing standards for guidance." This means that FDA will likely examine existing standards for laboratories, including ISO 17025, but the Secretary has the authority to establish an independent program for laboratory accreditation that may or may not bear resemblance to the requirements of ISO 17025.

- **Will the accreditation apply only to 3rd party labs, or in-house labs?**
    - FSMA states that the accreditation will be available to laboratories "including independent private laboratories and laboratories run and operated by a Federal agency (including the Department of Commerce), State, or locality with a demonstrated capability to conduct one or more sampling and analytical testing methodologies for food."

    - The language in FSMA does not specifically exclude in-house laboratories from being accredited, but given the very specific role of "accreditation" in the context of FSMA, accreditation of in-house laboratories is unlikely because it would seem to be a conflict of interest for in-house labs to conduct testing for regulatory purposes. As described below, this is the only FSMA-prescribed use for accredited labs.

- **When will the food industry be required to use these "accredited laboratories"?**
    - FSMA specifies the very limited circumstances in which the use of "accredited laboratories" would be required. These include:
        - in response to a specific testing requirement under this Act or implementing regulations, when applied to address an identified or suspected food safety problem; AND
        - as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem; OR
        - in support of admission of an article of food under section 801(a); AND under an Import Alert that requires successful consecutive tests.

    So what this means with the regulations as they stand today is that the only requirement for using accredited labs will be in the context of "regulatory testing" which today relates to food being held as part of a Detention Without Physical Examination as part of an import alert. Today testing in these circumstances is done by third party labs and it will be these labs doing this type of testing who will need to be accredited under FSMA.

    - Based on the language contained within the Act itself, the vast majority of testing: testing of raw materials, finished products, and the environment; will not be required to be performed by accredited laboratories. The issue of "accredited laboratories" will not change a company's current approach to testing.

- **The currently proposed Produce Safety Rule contains some testing requirements. Will these require farms to use accredited laboratories?**
    - Based on the proposed regulations and what FDA has said the answer to this question is no. In addition, while the Agency recommends methods that could be used to meet the testing requirements, flexibility is offered. For example, in proposed § 112.152, which asks "What methods must I use to test the growing environment for *Listeria* species or *L. monocytogenes*?" FDA references the methods and procedures described in Chapter 10 of FDA's Bacteriological Analytical Manual (BAM) April 2011, Edition (Edition 8, Revision A, 1998), or a method that is at least equivalent in accuracy, precision, and sensitivity.

    - This demonstrates that it is the Agency's overriding concern and advice that it is critical that a validated method be used in the hands of a proficient user. It does not matter if this is done by a 3rd party or in-house and it does not matter with regard to FSMA if that laboratory is accredited or not.

- **Will the final Preventive Control Rules for either human food or animal food require environmental or finished product testing?**
    - FDA is expected to release specific portions of the proposed preventive control rules for additional public comment. Many stakeholders believe that the new pieces will address environmental and/or finished product testing. TAG believes that the Agency will likely require environmental testing for pathogens in specific, high risk circumstances, for example during the production of ready-to-eat foods that are exposed to the environment. We expect that such testing could be used as a form of verification of sanitation.

    - There is less certainty around whether or not there will be a requirement to test finished products as a means of verification that the food safety system is functioning properly. However, many companies do test above and beyond regulatory requirements, and often testing is done to satisfy customer requirements.

- **If the Preventive Control Rules requires testing, must that be done by an "accredited laboratory"?**
    - For several reasons, we think it is extremely unlikely that any testing requirements (that are part of the final Preventive Controls Rules) will require the use of an "accredited laboratory".
        - First, it would be inconsistent of the FDA to require testing by accredited labs in the Preventive Controls Rules but not in the Produce Safety Rule.

        - Second, it appears that the cost of testing was a major reason that testing requirements were not specified in the first versions of the proposed rules. Requiring that tests be conducted by accredited laboratories will likely be more costly than the variety of methods that exist today (in house testing and the use of on or off-site third party labs). The economics of using accredited labs lead us to believe that FDA will not mandate this.

        - Additionally, FSMA's own restrictions on when accredited labs are to be used (for regulatory purposes only) leads us to believe that that testing requirements related to the verification of food safety programs will not qualify as "a specific testing requirement under this Act [FSMA] or implementing regulations [the Preventive Controls Rules], when applied to address an identified or suspected food safety problem". By definition, verification does not address an identified or suspected food safety problem;

        - Lastly, FDA has not established the process to accredit labs yet. The final Preventive Control Rules must be published by August 31, 2015, and larger companies will need to be in compliance within one year. From a practical

standpoint, it is unlikely that the accredited laboratory system will be established and fully functional by that time.

- **Do any sections of FSMA require that laboratory tests be performed by 3rd party laboratories? Is there any indication that in-house testing will be negatively impacted by FSMA rules?**
    - The answer to both these question is no. Thus far, only the proposed Produce Safety Rule mentions testing requirements, and the preamble to that rule clarifies that third party labs do *not* need to be used.

Rules that have been proposed to implement other parts of FSMA, such as the Preventive Controls Rules and Foreign Supplier Verification Program (FSVP) mention or are expected to mention testing. For example, FSVP mentions that an importer may deem it appropriate to require a certificate of analysis, or conduct testing of imported products. In neither instance does FDA place any restrictions on labs performing these tests.

- **Will 3rd party labs be required to share test results with FDA?**
    - In general, the answer is no. Food companies can continue to work with 3rd party laboratories as they normally do.

    - It is only when accredited laboratories MUST be used that "The results of any such testing shall be sent directly to the Food and Drug Administration, except the Secretary may by regulation exempt test results from such submission requirement if the Secretary determines that such results do not contribute to the protection of public health. Test results required to be submitted may be submitted to the Food and Drug Administration through electronic means." As noted previously, the instances in which accredited laboratories must be used are very limited.

    - If an accredited laboratory is used for non-regulatory testing, then our interpretation of FSMA is that these results would not automatically be shared with FDA.

    - Companies should bear in mind that FDA's access to company records has been expanded and the criteria to request records has been lowered by FSMA. FDA has access to test results when they believe there is a reasonable probability that a food is adulterated and may cause serious adverse health consequences. It does not matter if the test was performed in house or by a third-party laboratory: FDA has access to these records.

Conclusion

Because of FSMA's complexity, it is easy to confuse certain sections of FSMA with others. Also, given that all of the rules are in proposed form, speculation abounds around what will be required once the rules are finalized. What FSMA says about laboratories and methods of analysis, and how FDA will interpret and apply these, has been continually misinterpreted.

To be clear:

- None of the proposed rules would require the use of a third party laboratory
- None of the proposed rules would require the use of an "accredited laboratory"
- The term "accredited laboratory" as used in FSMA has nothing to do with ISO 17025 accreditation; this would be an independent FDA-established program
- FDA has not yet established a program for accrediting laboratories
- FDA will not require laboratories to report test results to FDA unless the tests are required such as to satisfy the requirements of import alerts