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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 has required the FDA to develop numerous rules. The seven pillars of FSMA have been released as final rules. Questions among industry remain regarding the role of testing and its applicability to FSMA. Clarification in the final rules has answered some of the 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?**
- **Does 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 Produce Safety Rule contains some testing requirements. Do these require farms to use accredited laboratories?**
- **Does the final Preventive Controls Rule for Human Food and the Preventive Controls Rule for Animal Food require environmental or finished product testing?**

- **Must testing under the Preventive Controls Rule for Human Food and Preventive Controls Rule for Animal Food, be done by an "accredited laboratory"?**
- **Do any sections of FSMA require that laboratory tests be performed by 3rd party laboratories? Is in-house testing negatively impacted by FMSA rules?**
- **Are 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.

- **Does the accreditation apply only to 3rd party labs, or in-house labs?**
    - FSMA states that the accreditation is 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.

    This means that with the regulations as they stand today, 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 Produce Safety Rule contains some testing requirements. Will these require farms to use accredited laboratories?**
    - Based on the final 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 section § 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.

- **Does the final Preventive Control Rules for either human food or animal food require environmental or finished product testing?**
    - The major provision of the final rule describes product testing and environmental monitoring listed as possible verification activities, but, like other preventive controls or management components in general, they are only required as appropriate to the food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system. In some cases, neither product testing nor environmental monitoring will be appropriate. For example, there would be little to no benefit to product testing or environmental monitoring in facilities that pack or hold produce or raw agricultural commodities that are rarely consumed raw, such as potatoes.

    - For example, environmental monitoring would be required to verify effectiveness of sanitation controls when an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a step or process lethal to the pathogen) that would significantly minimize the pathogen, or because such environmental monitoring is appropriate to the facility (one manufacturing RTE foods), the food (an RTE food exposed to the environment), and the nature of the preventive control (sanitation controls). Foods such as peanut butter, soft cheeses, dried dairy products for use in RTE foods, and roasted nuts are among the products for which manufacturing operations would need to have an environmental monitoring program when such foods are exposed to the environment.

- **Must testing under the Preventive Controls Rule for Human Food and Preventive Controls Rule for Animal Food, be done by an "accredited laboratory"?**
    - Routine testing does not have to be conducted by an accredited laboratory, but the test method(s) must be scientifically valid, and results do not have to be sent to the FDA.

- **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. The Produce Safety Rule requires testing of water that is used in agriculture with different requirements in different situations. Also, as already noted the Preventive Control Rules require environmental monitoring on specific circumstances.

Rules that have been finalized to implement other parts of FSMA, such as the Preventive Controls Rules and Foreign Supplier Verification Program (FSVP) 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 the 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. The 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: The FDA has access to these records.

Conclusion

Because of FSMA's complexity, it is easy to confuse certain sections of FSMA with others. 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 finalized rules require the use of a third party laboratory
- None of the finalized rules 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