July 6, 2020

Submitted electronically at regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Proposed Rule: Laboratory Accreditation for Analyses of Food (Nov. 4, 2019); Docket No. FDA-2019-N-3325

FMI appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the "Laboratory Accreditation for Analysis of Foods" proposed rule. We appreciate FDA's work developing and implementing the FDA Food Safety Modernization Act (FSMA) regulations and the outreach from the FDA to all stakeholders that has allowed for the food industry to appropriately implement these regulations.

About FMI

As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org

Overview

FMI supports the goal of the laboratory accreditation program established by FSMA. Implementing this program will help FDA improve the safety of the US food supply and protect consumers by helping ensure that certain food testing connected with particular

public health risks is conducted by laboratories that maintain high standards and apply proper scientific methods.

We encourage the FDA to adhere to the statutory limitations of FSMA and develop a program that is narrowly focused on testing for certain imports and for foods with identified or suspected food safety problems. We are concerned that the proposed new enforcement tool of food testing orders goes beyond the confines of the statute and could provide the wrong incentives for testing.

When developing this new laboratory accreditation program, it is important for FDA to consider the significant policy objective of encouraging food facilities to engage in robust routine environmental monitoring. Accordingly, FDA should not establish a system whereby routine testing results could trigger the need for a Food Testing Order and the use of accredited laboratories under this program. This approach would discourage companies from adopting a seek and destroy testing mentality. Furthermore, testing should be used by facilities to support their food safety programs, so testing requirements should not be applied punitively as a regulatory tool.

In the comments that follow, we elaborate on our concerns about food testing orders and comment on other aspects of the proposed rule.

Approach to Laboratory Accreditation

Standards for laboratories has advanced over the past decades and many systems are in place to assure a high level of integrity and adherence to scientific best practices. Standards assure that laboratories operate competently and generate valid results. A standard that is accepted worldwide is ISO/IEC17025. When product sampling is necessary, FMI recommends that our members ask for laboratories to be accredited to ISO/IEC17065 and for the appropriate methodology to be listed on the laboratory's Scope of Accreditation.

We encourage the FDA not to codify a private standard, but to recognize the significant benefit that comes with adherence to a rigorous private standard such as ISO/IEC17065. There is tremendous benefit in allowing laboratories that meet the requirements of such standards to be recognized as meeting the requirements of the FDA regulation. Having any conflicts between the regulation and the acceptable ISO/IEC standard would cause significant business and operational challenges for laboratories and the users of laboratory services.

Private standards change over time, so we encourage the FDA to allow for flexibility in allowing for multiple ways to meet the requirements of the regulation. At this time, ISO/IEC17065 is the predominant standard for the laboratory industry but in a decade or two, that might change. We recommend consistency but flexibility when regulations reference private standards.

We encourage FDA to work with ISO, AOAC, ANSI and other leading standard and scientific organizations to make sure that accreditation requirements are aligned and are focused on scientific integrity.

Additionally, because there already are many laboratories accredited under the existing industry-developed standards, we strongly encourage the FDA to change the definition of "accredited laboratory" in the proposed rule to "section 422 accredited laboratory" to prevent confusion with these laboratories that already have existing accreditations. We have seen confusion in the past when different rules use similar definitions and encourage the FDA to be as specific as possible with this definition.

Food Testing Orders Should Not Be Included in the Regulation

The proposed rule establishes a new enforcement tool whereby FDA could issue a "food testing order" under which testing would need to be performed by an accredited lab. This tool was not established by FSMA section 202 and goes far beyond the purpose of this statutory provision. Accordingly, FMI opposes inclusion of food testing orders in the final rule. Below we outline our concerns with food testing orders and offer recommendations for how this mechanism could be improved if FDA does not adopt our recommendation to omit food testing orders from the final rule.

Facilities already must conduct environmental and product testing and share those results with FDA. As mentioned above, we are concerned that the prospect of food testing orders being triggered by routine testing results could deter facilities from implementing robust "seek and destroy" environmental monitoring programs. We also question why this enforcement tool is needed given that the agency already has the authority to sample products and the environment and have the testing performed by an FDA laboratory. The agency provides no explanation in the preamble regarding the need or justification for food testing orders.

From a more practical angle, we are concerned that the food testing order proposal is not fully developed. There are many open questions about practical issues related to how food testing orders would work. For example:

- Who can issue a food testing order? The proposed rule only states that "FDA" can do so. This is a significant authority that should be limited to only the FDA Commissioner and should not be delegable.

- Under what circumstances can a food testing order be issued? In the preamble, FDA states that an article of food that violates a provision of the Act that relates to food safety could constitute an "identified or suspected food safety problem." However, the agency also states that a violation is not required and a "food safety problem" may nevertheless be present absent a violation. This is very vague and does not provide industry with the necessary certainty and clarity about the limitations on use of this authority. It is important that food testing orders only be used in circumstances where there is a public health need for the testing results to be sent directly to FDA by a laboratory accredited under this program.

- Operationally, how is a food testing order issued and to whom is it provided? Would the food testing order be provided to a corporate parent, a facility, or some other location? How would it be delivered – electronically, in-person, or by mail? How would FDA issue a food testing order when there are multiple owners or consignees? In light of the proposed 24-hour window for appealing an order, it is imperative that FDA clarify who will receive a food testing order and explain the delivery process.

- How long would a food testing order last and how would it be terminated? The proposed rule is silent on both of these issues, and this lack of detail presents significant due process concerns. At a minimum, a food testing order should terminate when the identified or suspected food safety problem is resolved. We also urge FDA to provide owners or consignees with the opportunity to present evidence showing the problem has been resolved and that the food testing order is no longer necessary or appropriate.

- Would test results also be sent to the owner or consignee? This issue also is not addressed by the proposed rule. FMI recommends that the regulation provide that an accredited laboratory can send the results to FDA and the owner or consignee simultaneously.

- Would food testing orders be made public? We recommend that they should not be publicized because there is no action for anyone to take in response to such results, other than the owner or consignee of the food.

- Could the food testing order provision come into force before there is sufficient laboratory capacity and/or if there are not validated methods for the applicable test/food matrix combination? It is unclear whether a food testing order could be ordered for a test method that has not yet been validated, and whether the entity receiving the food testing order would then be responsible for validation of the test method. This could be a very costly and time-intensive endeavor, as validation of a single method can take many months and cost hundreds of thousands of dollars. FMI believes it would be inappropriate for a food testing order to be issued for a test and/or food matrix that has not already been validated with an available accredited laboratory.

In light of these concerns, FDA should either remove the food testing order proposal entirely from the final rule, or issue a re-proposal with a clear and limited scope. FMI maintains that if food testing orders are included in the final rule, they should be:

- Reserved for situations where a serious food safety concern (a SAHCODHA hazard) has been established and a substantiated concern that the laboratory being used is inadequate, such that the testing needed "to address" the problem and determine whether it has been resolved needs to be performed by an accredited lab with the results sent to FDA;
- Limited to product testing (not environmental testing);
- Only be issued where a validated method and accredited laboratory are available for the specific food matrix;
- Issued by the FDA Commissioner and not further delegated; and,
- Addressed through a mandatory (not discretionary) hearing process, if requested by the food owner.

These limitations are necessary to ensure that food testing orders are tied to the purpose of and language in the lab accreditation provision in FSMA, are practical to implement, and have appropriate due process protections in place.

Additional Comments

FMI also offers the following feedback on other aspects of the proposed rule:

- We agree with FDA's conclusion that routine testing conducted under a food safety plan is not testing "applied to address an identified or suspected food safety problem" and that such testing is not required to be conducted by an accredited lab under the rule.

- We agree with FDA that this rule should not require accreditation of samplers. Sampling accreditation is not sufficiently developed to apply this requirement, nor do we believe requiring such accreditation would have a material benefit.

- There are many quality in-house laboratories and they should have the option of becoming accredited under the rule. However, they also should not be required to be accredited. There is great benefit to having in-house laboratories to be able to run chemical and microbiological analyses quickly.

- The rule should only cover product sampling and should not apply to environmental sampling.

- We agree with the FDA that this rule should not apply for testing associated with the Foreign Supplier Verification Programs (FSVP) regulation.

- We also agree with the FDA that a phased in approach would the be best way to implement this rule. Historically, the laboratory accreditation process has taken time to operationalize. FDA should not implement the proposed rule and require testing to be conducted by accredited laboratories until there is a sufficient capacity of accredited laboratories to carry out required testing in a timely manner. Further, the agency needs to consider that testing capacity may be available for some tests and food matrixes before others, so it may need to take a further phased approach based on the capabilities of the laboratories that gain accreditation under this rule.

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Maintaining robust scientific standards for laboratories performing food-related testing is of great interest to FMI member companies. We encourage the FDA to optimize the

use of existing standards and trusted business practices as the agency implements this new program, while also adhering to the boundaries established by the law.

Please feel free to contact us should you have questions about these comments or need additional information from FMI.

Sincerely,

Hilary Thesmar, PhD, RD, CFS
Chief Food and Product Safety Officer and SVP Food Safety