

MEMORANDUM

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Re: **FDA Issues Laboratory Accreditation Proposed Rule Required Under FSMA**

The U.S. Food and Drug Administration (“FDA”) recently issued a proposed rule entitled “Laboratory Accreditation for Analyses of Foods” (“Proposed Rule”), which was mandated by the FDA Food Safety Modernization Act (FSMA). ^{1/} The Proposed Rule establishes a new program whereby certain food testing must be performed by laboratories accredited by an FDA-recognized accreditation body. The accredited laboratories would be required to send the results of testing conducted under this rule directly to FDA.

FDA proposes that use of an accredited laboratory would be required: (1) for nine specific existing regulatory testing requirements that apply to bottled water, shell eggs, and sprouts; (2) if the agency issues a “food testing order;” (3) for certain test results presented to FDA in connection with certain serious agency enforcement actions (e.g., mandatory food recalls); and (4) for certain testing involving imports. A food testing order would be a new regulatory tool whereby FDA would have broad authority to require an owner or consignee of food to perform food product or environmental testing in response to an identified or suspected food safety problem.

This memorandum summarizes the key aspects of the Proposed Rule, with a focus on the impacts on food manufacturers and importers. Note that the preamble includes a number of tentative conclusions and questions for comment that warrant careful review, but which are beyond the scope of this memorandum. Comments on the Proposed Rule are due March 3, 2020. ^{2/}

I. Background

Section 202 of FSMA requires FDA to establish a program for testing food by accredited laboratories, whereby FDA-recognized accreditation bodies would accredit laboratories that must be

^{1/} 84 Fed. Reg. 59452 (Nov. 4, 2019).

^{2/} Comments should be submitted to Docket No. FDA-2019-N-3325.

used to perform certain food testing and must provide those testing results directly to FDA. ^{3/} The law provides that accredited laboratories must be used whenever designated food testing is conducted:

- A. “By or on behalf of an owner or consignee—
 - (i) in response to a specific testing requirement under [the FFDCA] or implementing regulations, when applied to address an identified or suspected food safety problem; and
 - (ii) as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem; or

- B. on behalf of an owner or consignee—
 - (i) in support of admission of an article of food under [FFDCA] section 801(a); and
 - (ii) under an Import Alert that requires successful consecutive tests.” ^{4/}

The law also includes provisions on issues such as establishing model laboratory standards and establishing a public registry of accreditation bodies and accredited labs.

II. Overview of Proposed Rule

A. Scope

The Proposed Rule has potential applicability for the following three stakeholder groups:

1. Accreditation Bodies – An accreditation body would be subject to this regulation if it has been recognized by FDA to accredit laboratories to conduct food testing under this regulation.

2. Laboratories – A laboratory would be subject to the regulation if it has been accredited by a recognized accreditation body to conduct food testing under this regulation, and conducts any testing required under this regulation. Both independent laboratories and laboratories owned by an owner or consignee (i.e., in-house laboratories) can participate in the laboratory accreditation program. The preamble and language of the proposed rule imply that accredited laboratories would only be required to send testing results to FDA when the testing occurs under the scope of this regulation.

3. Owners and Consignees – The Proposed Rule would apply to an “owner or consignee” that is required to use an accredited laboratory to conduct food testing under this regulation. FDA defines this term to mean “any person with an ownership or consignment interest” in the food product or environment that triggers the need for testing under this proposed regulation. The triggers for testing are discussed below.

The rule would cover “food testing,” which FDA proposes to define as the analysis of both food product samples and environmental samples.

^{3/} The requirements in FSMA § 202 are codified in Section 422 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 350k(a)).

^{4/} FFDCA § 422(b)(1).

B. Circumstances Requiring Food Testing to be Conducted by An Accredited Laboratory

As explained above, the statute establishes limitations on when testing must be conducted by an accredited laboratory, with a key trigger for non-imported foods being whether there is an “identified or suspected food safety problem.” FDA explains in the preamble that “[b]ecause the circumstances that may constitute a food safety problem are highly fact dependent, [the agency is] not proposing an exhaustive list of circumstances that would constitute an ‘identified or suspected food safety problem.’” FDA also explains that the agency has tentatively determined that an “identified food safety problem” could be present where there is a reasonable suspicion that a specific article of food violates a provision of the FFDCFA that relates to food safety, or where there is particularized suspicion of a food safety problem that does not necessarily render food violative.”

Accordingly, the Proposed Rule provides that food testing must be conducted under this regulation whenever such testing is conducted by or on behalf of an owner or consignee in the following situations:

1. In response to explicit testing requirements that address an identified or suspected food safety problem, which are contained in the following existing regulatory provisions:
 - (i) Bottled drinking water—21 CFR § 129.35(a)(3)(i) (for the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli*);
 - (ii) Sprouts—21 CFR § 112.146(a), (c) and (d); and
 - (iii) Shell eggs—21 CFR §§ 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e). 5/
2. As required by FDA in a food testing order;
3. To address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing prior to the issuance of a mandatory food recall order, as part of a corrective action plan after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order;
4. In support of admission of an article of food under section 801(a) of the FFDCFA; 6/ and
5. To support removal from an import alert through successful consecutive testing. 7/

Each of these situations is explained in more detail below.

5/ FDA also is proposing a conforming change to 21 CFR § 129.35(a)(3)(iii) to clarify that the explicit testing requirement in § 129.35(a)(3)(i) that addresses an identified or suspected food safety problem must be conducted under this proposed program, which would require, in pertinent part, the laboratory conducting the testing to be accredited under this program.

6/ Food testing conducted on articles of food offered for import into the United States under FFDCFA § 801(a) may only be conducted after the food has arrived in the United States, unless FDA has determined, and responded in writing to the owner/consignee, that a sample taken prior to arrival is or would be representative of such articles offered for import into the United States.

7/ The limitation on foreign testing in the prior footnote also applies to testing conducted to support removal from an import alert through successful consecutive testing.

When food testing is conducted in these circumstances, testing must be performed by accredited laboratories that are accredited by a recognized accreditation body for the appropriate analytical method or methods. Accordingly, laboratories can be accredited for different purposes and cannot necessarily all be used interchangeably.

Notably, FDA would not require routine or verification testing, such as environmental monitoring or product testing under a Food Safety Plan (for the Preventive Controls rules), to be conducted by an accredited laboratory because such testing is “not conducted to address a suspected (or identified) food safety problem.” Nonetheless, FDA explains that the results from such testing may provide the basis for a suspected or identified food safety problem that could lead to the issuance of a “food testing order” that would fall under this new regulation.

1. Testing Under Specific Existing Regulatory Requirements

Because the statute applies to “specific” testing requirements, FDA proposes to identify provisions of its regulations that explicitly require food testing related to an “identified or suspected food safety problem,” and therefore would trigger the requirement to use an accredited laboratory. The agency has identified nine explicit testing requirements in its regulations that it tentatively concludes address an identified or suspected food safety problem because they each require testing as a follow-up, or corrective action, after a routine test is positive for a pathogen or indicator organism.

As set out in the section above, five of these testing requirements are in the regulations on production, storage, and transportation of shell eggs, three are in the standards for the growing, harvesting, packing, and holding of sprouts, and one is in the regulations on the processing and drinking of bottled drinking water.

2. Food Testing Orders

FDA proposes establishing a new regulatory tool called a “food testing order” that would require the use of an accredited laboratory. This tool is not established by the statute, but rather the agency concluded that the law grants FDA discretion to implement such a requirement. The Proposed Rule provides that “FDA may require the owner or consignee of an article of food to conduct food testing, or to have food testing conducted on their behalf, under this [regulation] to address an identified or suspected food safety problem related to the article of food.”

In the preamble, FDA explains that it is not proposing an exhaustive list of circumstances that would constitute an “identified or suspected food safety problem,” though the preamble provides some broad guardrails. More specifically, the agency explains that the element of suspicion in a “suspected food safety problem” typically needs to be “particularized,” meaning there is a basis in fact about a particular food (e.g., lot or batch) or food production environment (e.g., a specific facility), as opposed to common characteristics of a food (e.g., whether it is inherently high risk). The preamble also includes the following examples:

- Identified or Suspected Food Safety Problem:
 - The presence of *Listeria monocytogenes* on a food-contact surface.
 - The presence of multiple positives for *Listeria* spp. on a food-contact surface.
 - Potential contamination events.

- Not Necessarily an Identified or Suspected Food Safety Problem:
 - A positive indicator organism test (e.g., a single positive *Listeria* spp. on a food-contact surface).
 - Routine product testing and environmental monitoring results under the Preventive Controls rules.

The Proposed Rule also provides that a food testing order will specify the food product or environment to be tested; whether the food testing may be conducted using an accredited laboratory that is owned, operated, or controlled by the owner or consignee; the timeframe in which the food testing must be conducted; and the manner of the food testing, such as the methods that must be used.

Finally, a food testing order will constitute notice of an opportunity for hearing under 21 CFR Part 16. Accordingly, an affected owner or consignee may request a regulatory hearing on a food testing order. FDA proposes that this request must be submitted “no later than 24 hours after the time at which FDA issued the food testing order.” The request for a regulatory hearing must be submitted with a written appeal that responds to the bases for the agency’s determinations described in the food testing order, together with any supporting information upon which the requestor is relying. After a request for a regulatory hearing is granted, it would need to be held within 2 business days.

3. Testing in Connection with Certain Serious Enforcement Actions

Testing presented to FDA in connection with certain serious agency enforcement actions also would need to be conducted under this rule. Specifically, testing conducted to address an identified or suspected food safety problem and presented to FDA in the following three instances would be required to be conducted by an accredited laboratory:

- As part of evidence for a hearing prior to the issuance of a mandatory food recall order,
- As part of a corrective action plan after an order suspending a food facility’s FDA registration, and
- As part of evidence submitted for an appeal of an administrative detention order.

These are among the most serious of FDA’s enforcement powers the agency gained under FSMA and are used infrequently.

4. Import-Related Testing

Two of the situations requiring the use of accredited laboratories relate to imports. First, FDA would require use of an accredited laboratory “in support of admission of an article of food under [FFDCA] section 801(a).” This provision of the statute provides FDA with broad authority to refuse admission of food for reasons that include if the food “appears” to be adulterated, misbranded[, or manufactured, processed, or packed under insanitary conditions.] Accordingly, if an import entry is detained under this provision of the Act, the owner or consignee would need to use an accredited laboratory under this program in order to use the test results as evidence supporting admission. However, FDA has determined that use of accredited laboratories would not be required in connection with Foreign Supplier Verification Program (FSVP) compliance, even though the FSVP rule is cross-referenced in the statute as grounds for refusing admission under section 801(a).

Second, FDA proposes that food testing must be conducted under this regulation when it is conducted on behalf of an owner or consignee to support the removal of food from an import alert

through successful consecutive testing. An import alert enables FDA to detain imported food that appears to violate the FFDCA without first performing a physical examination of the food. The agency proposes that, with one exception, such testing may only be conducted on samples taken after the food has arrived in the United States. The exception would be for circumstances when FDA determines that a sample taken prior to arrival is representative of the imported food, which is a determination the agency would make on a case-by-case basis based on clear evidence that the product sampled and analyzed is actually the product offered for import.

C. Requirements for Accreditation Bodies and Accredited Laboratories

The Proposed Rule contains detailed eligibility requirements for accreditation bodies and laboratories, which warrant careful review by any entities seeking to become accredited. A few key points of interest are discussed below:

- **Standards:** FDA is proposing to require accreditation bodies to meet the requirements under ISO/IEC 17011: 2017 in their entirety. Accredited laboratories would be required to meet certain aspects of ISO/IEC 17025:2017, however they would not be required to meet the requirements of ISO/IEC 17025:2017 that relate to the relationship between the laboratory and its customers.
- **Sampling:** In the preamble, FDA explains that the agency carefully considered whether to include a sampling accreditation requirement in the Proposed Rule. The agency decided against proposing such a requirement, but “strongly encourage[s] all samplers to consider accreditation.” The agency also states that it may reassess its position after accreditation bodies have gained experience with accrediting entities that only conduct sampling. The agency also specifically requests comments on this matter.

Although the agency would not require samplers to be accredited, the Proposed Rule includes requirements related to sampling that apply to the accredited laboratories. Before analyzing a sample, the accredited laboratory would be required to develop (if it collected the sample) or obtain (if another entity collected the sample): (1) written documentation of the sampler’s applicable qualifications by training and experience; (2) a written sampling plan used to conduct the sampling; and (3) a written sample collection report for each sample collected that includes, among other things, documentation of sample collection procedures and any sample collection techniques and documentation of the chain of custody of the sample(s).

Additionally, FDA proposes to require advance notice of sampling in certain circumstances, which would need to be submitted to FDA 48 hours prior to collection of samples. This would allow the agency time to determine whether to observe the sampling and/or take an audit sample, and assign appropriate personnel to the task.

- **Scope of Accreditation:** The Proposed Rule provides that laboratories must obtain accreditation on a per-method basis. FDA interprets the statute to mean that a laboratory may become accredited even if it only seeks to be accredited for a single test method. Accordingly, the Proposed Rule provides that a laboratory seeking accreditation must demonstrate that it is capable of conducting each method of food testing for which it seeks to be accredited. Thus, an accredited laboratory is only permitted to perform testing under the

rule that is within the scope of its accreditation. FDA is not proposing a defined inventory of possible scopes, but rather laboratories would be able to become accredited for a variety of food analytical methods.

Additionally, in the preamble FDA tentatively concludes that independent laboratories and laboratories owned by owners or consignees alike may be accredited to conduct food testing. Thus, an in-house laboratory would be able to gain accreditation under the rule.

- Abridged Analytical Reports: FDA proposed two different levels of detail in the reporting of test results: full analytical reports and abridged analytical reports. FDA has proposed that only accredited laboratories that have fulfilled certain conditions may submit abridged analytical reports under this program, and in certain circumstances FDA may require even these accredited laboratories to submit full analytical reports. FDA is most likely to invoke this full analytical report requirement where the analysis is for an analyte that presents a relatively high risk to public health (e.g., *Clostridium botulinum*) or if something appears to be amiss in the abridged report. Conversely, FDA proposes that those laboratories which have not fulfilled certain conditions would have to submit full analytical reports on a routine basis.

D. Implementation

FDA explains in the preamble that implementation of the laboratory accreditation program will necessarily need to occur in a stepwise fashion. FDA would announce when, after the effective date of the final rule (which would be 60 days after its publication), the agency is prepared to accept applications for recognition from accreditation bodies. The agency would announce when it has recognized a sufficient number of accreditation bodies, at which point laboratories could then apply to the recognized accreditation bodies for accreditation. FDA would publish in the Federal Register, at least 6 months in advance, notice that it has attained sufficient laboratory capacity, such that owners/consignees in the circumstances described in the Proposed Rule would be required to utilize laboratories accredited under this program.

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Hogan Lovells is available to assist with analysis of the Proposed Rule and developing comments to the agency. Please contact us if you have any questions.