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WATER
ACTION** 

July 6, 2020

The Honorable Stephen M. Hahn
Commissioner
Food and Drug Administration
c/o Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Laboratory Accreditation for Analysis of Foods (Proposed Rule) FDA-2019-N-3325

The undersigned food safety and consumer groups submit these comments in support of the U.S. Food and Drug Administration (FDA) proposed rule on Laboratory Accreditation for Analysis of Foods (“the Proposed Rule”).¹ The Proposed Rule, promulgated under new authority created by the Food Safety Modernization Act (FSMA), is a step towards improving the reliability of testing used to ensure food safety. Such testing is vital to identify the presence of harmful pathogens, allergens, and chemical contaminants in food and will be particularly important for strengthening the safety of imported food.

However, we are concerned that the agency has construed its authority too narrowly, requiring accredited testing only in a few circumstances outside the context of food imports. For foods produced domestically, the Proposed Rule requires accredited testing only in rare formal proceedings or in relation to specific rules for shell eggs, sprouts, or bottled water. By failing to cover other domestic testing, the agency has fallen short of addressing important food safety problems as Congress intended under FSMA.

Ideally, all food testing would be carried out by laboratories accredited to the ISO/IEC 17025:2005 standard. At a minimum, we urge the FDA to expand the scope of the Proposed Rule to require laboratory accreditation for any testing undertaken to comply with regulatory requirements, particularly testing used to verify the effectiveness of food safety controls or to take corrective action when problems are identified under the agency’s rules on preventive controls and foreign supplier verification.

¹ Food and Drug Administration (FDA). Laboratory Accreditation for Analysis of Foods (Proposed Rule). 84 *Fed. Reg.* 59452 (November 4, 2019). [hereinafter “Proposed Rule”]

I. The Proposed Rule Includes Needed Measures to Strengthen the Safety of Imported Food

Congress, through FSMA, added Section 422 to the federal Food, Drug, and Cosmetic Act (FDCA), which authorizes the FDA to establish a program to accredit food testing laboratories and to require that testing be carried out by such laboratories under specific circumstances.

The statute describes the circumstances under which accredited testing will be required in Section 422(b)(1)(A) and (B), which authorize the FDA to require that testing be conducted by an accredited laboratory whenever such testing is conducted:

Under 422(b)(1)(A):

(A) by or on behalf of an owner or consignee--

(i) In response to a specific testing requirement under the FD&C Act or implementing regulations, when applied to address an identified or suspected food safety problem; and

(ii) As required by the Secretary of Health and Human Services, as the Secretary deems appropriate, to address an identified or suspected food safety problem...

And under 422(b)(1)(B):

(B) on behalf of an owner or consignee--

(i) in support of admission of an article of food under section 801(a)²; and

(ii) under an Import Alert that requires successful consecutive tests.

Section 422(b)(1)(B) focuses exclusively on imports, as Section 801(a) authorizes the FDA to refuse admission for foods that appear to violate the FDCA.

Enhanced reliability of import testing is sorely needed to ensure the safety of imported food. In its preamble to the Proposed Rule, the FDA discusses at length the need for an accreditation requirement to ensure the reliability of food import testing, detailing extensive challenges over many years in ensuring the quality of testing conducted by private laboratories on behalf of importers.³ For example, the agency describes “concerns... regarding importers’ manipulation or substitution of the samples a private laboratory tests, and practices such as ‘testing into compliance,’ in which multiple samples from a shipment are tested, but only those results that would allow the shipment to enter the United States are submitted...”⁴

The need for minimum standards to ensure the reliability of third-party testing of imports has also been illustrated by repeated outbreaks tied to imported foods. Notably, since 2011 the FDA has had in place an Import Alert for whole fresh papayas from Mexico, which requires third-party testing to verify that each shipment is free of *Salmonella* prior to allowing admission

² Codified as 21 U.S.C. Sec 381(a).

³ Proposed Rule at 59455-59457.

⁴ *Id.* at 59456.

into the United States.⁵ Yet the Import Alert does not require that this testing be carried out by an accredited laboratory, and the program has been ineffective at preventing outbreaks. Between 2011 and 2019, American consumers have been exposed to at least eight outbreaks caused by *Salmonella* serotypes linked to imported Mexican papayas, indicating that testing measures have failed repeatedly to prevent contaminated shipments from entering the country.⁶

While many measures, including measures beyond testing, are necessary to ensure the safety of imported foods, it is essential that, at a minimum, the FDA has the ability to ensure that testing submitted as a condition of entry under an Import Alert have been carried out by a reliable laboratory. The proposed rule is therefore an important step towards ensuring the reliability of such testing and the safety of imported food.

II. The Scope of the Proposed Rule should be Expanded to Require Accreditation for Verification and Corrective Action Testing

In addition to the import provisions laid out in 422(b)(1)(B), Congress in 422(b)(1)(A) granted broad discretion to the FDA to require accredited testing for food produced domestically. Yet the preamble to the current Proposed Rule proposes to apply an interpretation of 442(b)(1)(A) that dramatically narrows its scope to cover only a few testing circumstances outside the context of food imports.

We urge the agency to re-consider its interpretation and avoid improperly narrowing the scope of authority granted by Congress. At a minimum, the rule should ensure that verification and corrective action testing carried out as a means of meeting FDA regulatory requirements be performed by accredited laboratories, as these tests are critical to ensuring food safety.

A. The FDA Has Expansive Authority to Require Laboratory Accreditation Under FSMA

The FDA has expansive authority to require laboratory accreditation for domestic testing under 422(b)(1)(A), as the language of the statute is broad enough to encompass a wide variety of potential circumstances needed for prevention, detection, and response to foodborne illness.

In particular, 422(b)(1)(A)(ii) authorizes the agency to require testing “as the Secretary deems appropriate, to address an identified or suspected food safety problem.” This language potentially covers a variety of circumstances where either the FDA or businesses themselves have identified a food safety hazard and sought to address that hazard in part through testing. For example, food businesses regularly identify and seek to mitigate likely food safety hazards under the requirements for risk-based preventive controls mandated by FSMA. FDA inspectors also frequently identify hazards during routine or for cause inspections, and verification and corrective action testing may be employed by food businesses to assess whether the actions

⁵ FDA. Import Alert 21-17. March 10, 2020. www.accessdata.fda.gov/cms_ia/importalert_721.html. Certain importers are exempted from this requirement by virtue of placement on the “Green List.”

⁶ FDA. Statement calling on all sectors of the papaya industry to improve practices to better protect consumers. August 26, 2019. www.fda.gov/news-events/press-announcements/statement-calling-all-sectors-papaya-industry-improve-practices-better-protect-consumers.

taken to address those hazards have been effective. The FDA has authority under FSMA to deem accredited testing appropriate in these circumstances, yet the the Proposed Rule fails to do so.

B. The Proposed Rule Improperly Narrows the Scope of the FDA’s Authority to Cover Only Very Limited Testing Circumstances

Despite of the broad language in the statute, the FDA has dramatically narrowed its authority by reading additional restrictions into the statutory text that were not placed there by Congress.

Specifically, the agency has indicated that an “identified or suspected food safety problem” must be “particularized, that is, ha[s] a basis in fact about a particular article or articles of food (e.g., a lot or batch) or food production environment (e.g., a specific facility), as opposed to being satisfied by the common or usual characteristics of a food (e.g. whether a food is considered ‘high risk’ because of its inherent characteristics, such as pH or water activity) or the manner in which such food is typically produced.”⁷

Under this unnecessarily narrow reading, the FDA reasons that its authority under Section 422(b)(1)(A) would cover only a few testing circumstances. These are:⁸

- 1) Where follow-up testing is required after detection of a pathogen or indicator organism for rules related to shell eggs, sprouts, and bottled water.⁹
- 2) Where testing is submitted as evidence for proceedings involving mandatory recall orders, suspension of registration, or an administrative detention order.
- 3) As required by the FDA under a “food testing order,” a new type of order created under the Proposed Rule, which is issued to a specific owner or consignee for a specific period, and subject to opportunity for a hearing.¹⁰

Other than the testing for shell eggs, the number of tests covered under these additional provisions will be vanishingly small. In its own cost-benefits analysis, the agency estimated that while 10,708 to 15,110 tests would be performed annually for food imports, only 1,309 to 7,030 would be performed related to shell eggs, and only 25 to 30 would be performed related to sprouts and bottled water. The agency provided no estimate for the number of tests expected to be performed related to evidence submitted for proceedings involving recalls, suspension or detention, but noted “these situations would likely occur infrequently.” Indeed, such formal proceedings are rare; for example, the agency has issued only one mandatory recall order since this authority was granted under FSMA.¹¹

⁷ Proposed Rule at 59462.

⁸ Proposed Rule at 59461.

⁹ *Id.* at 59463.

¹⁰ *Id.* at 59466.

¹¹ Food and Drug Administration. FDA orders mandatory recall for kratom products due to risk of salmonella. April 3, 2018. https://www.fda.gov/news-events/press-announcements/fda-orders-mandatory-recall-kratom-products-due-risk-salmonella?utm_campaign=04032018_PR_Kratom%20recall&utm_medium=email&utm_source=Eloqua. The agency also issued letters notifying food companies of opportunity to initiate a voluntary recall on two occasions, in 2014 and 2013, as described in annual reports the agency is required to submit to Congress under

The FDA recognizes that under this approach, “many explicit testing requirements in our regulations are not subject to [the Proposed Rule].”¹² In particular, the agency notes that the proposal will exclude testing to verify preventive controls under 21 CFR § 117.165(a)¹³ and controls by foreign suppliers under 21 CFR § 1.506(d)(1).¹⁴ It even excludes testing conducted as part of corrective actions when an environmental pathogen or indicator organism is found during routine environmental or product testing.¹⁵

C. *The FDA Should Require Accreditation for, at a Minimum, Verification and Corrective Action Testing*

This narrow interpretation is not supported by the text of FSMA, which nowhere indicates that “an identified or suspected food safety problem” must be restricted to a particular article of food or facility. As the agency itself notes, the phrase “food safety problems” is used in two of the titles in FSMA: “Improving Capacity to Prevent Food Safety Problems (Title I)” and “Improving Capacity to Detect and Respond to Food Safety Problems (Title II).”¹⁶ These titles expansively cover numerous approaches to prevention, detection, and response and are not specific to addressing problems related to particularized facts about articles of food or food production environments. If Congress used such terms expansively in the titles to the statute, it follows that legislators would not have intended the same terms to be read so narrowly in Section 422.

Ensuring that verification and corrective action testing are performed by accredited laboratories is critical for food safety. For example, a Georgia egg facility run by Almark Foods Inc was implicated in a deadly *Listeria* outbreak announced in December of 2019 despite verification and corrective action testing that had recently been undertaken by a third-party laboratory in response to FDA inspectional findings.¹⁷ In that case, the Almark facility had been inspected by the FDA in February 2019 and the owners were warned in a letter by the agency that *Listeria* present in environmental samples had been matched to human cases of illness.¹⁸ In response, the owners of the Georgia facility pointed to negative third-party test results for contemporaneous samples from the same sites found to be positive by the FDA, as well as additional negative results for samples taken following corrective action. The owners also indicated that they had commissioned additional third-party laboratory testing to validate the

FSMA. Food and Drug Administration. FSMA Reports & Studies. <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-reports-studies>.

¹² Proposed Rule at 59463.

¹³ *Id.* at 59462.

¹⁴ *Id.* at 59464.

¹⁵ *Id.* at 59455 (stating that the proposed rule “would not apply to all corrective action testing,” but only to the specific provisions related to shell eggs, sprouts, and bottled water).

¹⁶ *Id.*

¹⁷ Centers for Disease Control and Prevention. Outbreak of *Listeria* Infections Linked to Hard-boiled Eggs. March 4, 2020. <https://www.cdc.gov/listeria/outbreaks/eggs-12-19/updates.html>.

¹⁸ FDA. Almark Foods Inc. Warning Letter. July 22, 2019. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/almark-foods-inc-576633-07222019>.

preservation methods in use in the facility.¹⁹

Yet, despite these steps, the Almark facility was implicated in a deadly outbreak later that year caused by the same *Listeria* strain that had been detected earlier by the FDA. The actions taken by Almark were clearly insufficient to prevent eggs produced at its facility from sickening consumers. And while FDA and Almark have not disclosed the name of the third laboratory involved in testing Almark's samples, the fact that its testing produced only negative results while FDA detected *Listeria* in swabs taken from the same locations suggests the quality of its testing program should be re-assessed.

The Almark outbreak illustrates a point that will already be abundantly clear to those who work in food safety: food safety testing must be reliable because human lives depend on the accuracy of the results. Yet the Proposed Rule would not have required the verification and corrective action testing ordered by Almark Foods to be performed by an accredited laboratory.

The FDA may have opted to exclude verification and corrective action testing from coverage under the Proposed Rule because such testing is not the sole means to verify the effectiveness of preventive controls.²⁰ Yet, should a facility choose to rely on such testing as a means of compliance with FDA rules, that testing is surely done "in response" to a regulatory requirement and should be covered under Section 422(b)(1)(A).

While not expressly stated in the Proposed Rule, the FDA also may be concerned that further expanding verification and corrective action testing would be more extensive and thus be a greater burden to industry than the testing required under the current Proposed Rule. Such concerns would be mitigated by providing ample time for industry to implement the new requirements. Furthermore, once implemented, broader testing and accreditation would help prevent outbreaks, thereby reducing economic disruption to industry, health costs to consumers, and the deaths that result from such outbreaks.

Even if the FDA decides not to require verification and corrective action testing at this time, we encourage the agency to re-visit its legal analysis and re-consider its authority under 422(b)(1)(A) to recognize that this provision could apply beyond the narrow framework laid out in the Proposed Rule. Such an interpretation would preserve the agency's authority to require additional accredited testing in the future as needed.

III. Conclusion

The undersigned groups support the Proposed Rule, which will help ensure the reliability of testing used to support food safety, particularly the safety of imported food. We urge the FDA

¹⁹ Almark Foods Inc. Response Letter. August 6, 2019. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/almark-foods-inc-576633-08062019>. The name of the laboratory that conducted the testing was redacted, and the letter does not disclose whether the laboratory was accredited.

²⁰ 21 CFR 117.165(a) ("product testing" and "environmental monitoring" are among several activities to "verify that the preventive controls are ... effectively and significantly minimizing or preventing the hazards."); 21 C.F.R. 1.506(d)(1) ("sampling and testing of a food" is listed among several "appropriate verification activities" that can be used to meet verification requirements for foreign suppliers.)

to move forward with the rule expeditiously, but also encourage the agency to re-consider its authority and expand the scope of the Proposed Rule to cover any testing relied upon to comply with regulatory requirements, particularly testing used to verify the effectiveness of food safety controls or to take corrective actions when food safety problems are identified.

Sincerely,

Center for Food Safety
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Consumer Federation of America
Consumer Reports
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