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MEMORANDUM

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Re: Lawsuit Seeks to Compel FDA to Implement FSMA's Laboratory Accreditation Provisions

Two consumer groups have sued the Food and Drug Administration (FDA) seeking to compel the agency to implement the laboratory accreditation provisions in the FDA Food Safety Modernization Act (FSMA). Specifically, the plaintiffs want FDA to meet its obligation under FSMA to establish a program for the recognition of accreditation bodies and accreditation of laboratories equipped to perform food safety testing, including developing model standards for laboratory accreditation. The lawsuit was brought in the U.S. District Court for the Northern District of California by the Center for Food Safety (CFS) and Center for Environmental Health (CEH). 1/

CFS and CEH previously sued FDA for failing to meet the statutory deadlines for other FSMA requirements. In 2012, the groups sued FDA after the agency did not meet the statutory deadlines for promulgating the seven major FSMA regulations. FDA settled the lawsuit by establishing a schedule of deadlines for completion of the rulemakings, and FDA subsequently issued the regulations by the court-ordered deadlines. In October 2018, the groups sued FDA for failing to meet the statutory deadlines for FSMA's traceability provisions. FDA entered into a consent agreement in June 2019 and agreed to implement the traceability provisions on a specified timeline. Neither of those lawsuits addressed the statutory deadlines related to laboratory accreditation that are at issue in this most recent lawsuit.

This memorandum first provides background on the accredited laboratory provisions under FSMA and then summarizes the complaint.

FSMA Laboratory Accreditation Requirements

Section 202(a) of FSMA requires FDA to establish a program for recognizing accreditation bodies and accredited laboratories qualified to perform food safety testing. 2/ Specifically, by January 4, 2013, FDA must:

1/ *Center for Food Safety v. Azar II*, No. 3:19-cv-05168 (N.D. Cal. Aug. 19, 2019). The complaint is available at https://www.centerforfoodsafety.org/files/2019-08-19--doc-01--complaint-fsma_56005.pdf.

2/ 21 U.S.C. § 350k (Federal Food, Drug, and Cosmetic Act § 422). This program for recognition of accreditation bodies and accreditation of laboratories to perform food testing is

1) Establish a program for the testing of food by accredited laboratories, including criteria for recognition of accreditation bodies;
2) Develop model standards that a laboratory must meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology;
3) Establish a publicly available registry of accreditation bodies recognized by the agency and laboratories accredited by a recognized accreditation body; and
4) Require, as a condition of recognition or accreditation, recognized accreditation bodies and accredited laboratories to report to FDA any changes that would affect their recognition or accreditation.

The model standards for laboratory accreditation must include methods to ensure that (i) appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate; (ii) internal quality systems are established and maintained; (iii) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited; and (iv) individuals who conduct the sampling and analyses are qualified by training and experience to do so.

FSMA also directs FDA to work with laboratory accreditation bodies to increase the number of laboratories that are qualified to perform testing of food.

Most significantly, no later than July 4, 2013, food testing must be conducted by laboratories that have been accredited for the appropriate sampling or analytical testing methodology by a recognized accreditation body on the registry established by FDA whenever the testing is conducted "by or on behalf of an owner or consignee" in the following circumstances:
1) "in response to a specific testing requirement under [the Federal Food, Drug, and Cosmetic Act (FFDCA)] or its implementing regulations, when applied to address an identified or suspected food safety problem;"
2) "as required by [FDA] to address an identified or suspected food safety problem;" or
3) "(i) in support of admission of an imported article of food under [FFDCA] section 801(a); and (ii) under an Import Alert that requires successful consecutive tests."

Testing by an accredited laboratory would not be required, however, for routine testing performed by facilities for compliance with the Preventive Controls regulations or with the Foreign Supplier Verification Programs regulations, for example.

The results of any of the required food testing must be sent to FDA, unless exempted by FDA by regulation on the basis that the results do not contribute to the protection of public health.

Finally, Section 202(a) requires that if food sampling and testing performed by a laboratory run and operated by a state or locality that is an accredited laboratory results in a state recalling the food, FDA must review the sampling and testing results for the purpose of determining whether a national recall or other compliance and enforcement activities are needed.

Summary of Complaint

According the complaint, Congress intended the laboratory accreditation provisions to establish a network of accredited laboratories to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards. The complaint notes that in the time that has lapsed since the statutory deadlines for the laboratory accreditation provisions, "devastating foodborne illness outbreaks have

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separate from the voluntary program for the accreditation of third-party certification bodies, also known as third-party auditors, to conduct food safety audits and issue certifications of foreign entities.

continued and spread across the country…." The plaintiffs argue that these outbreaks could have been prevented or lessened had FDA implemented the laboratory accreditation provisions.

The groups also argue that the FSMA laboratory accreditation provisions "are inextricably linked to and required for effective implementation of other statutory provisions," citing FSMA's requirement that FDA report to Congress on the integration of surveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks. They also point to a coalition letter submitted to FDA in July 2019 by several testing labs and consumer groups, which argues that these provisions of FSMA should be implemented because laboratory testing is a component of most of the FMSA final rules issued to date. 3/

The plaintiffs allege that FDA's "unlawful withholding and unreasonable delay of FSMA implementing actions" injures their organizations by putting their members' health and safety in increased jeopardy through the risk of contracting foodborne illness. They argue their members and their families have fallen ill as a result of foodborne illness outbreaks and that they pay a premium to make food from scratch and to buy organic products to reduce the risk of contracting a foodborne illness.

Additionally, the plaintiffs argue that FDA's failure to meet the laboratory accreditation provisions constitutes "unlawfully withheld and unreasonably delayed agency action" under the Administrative Procedure Act and FSMA, and they seek an order directing FDA to promulgate the regulations according to a court-ordered deadline.

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We will continue to monitor the litigation and FDA's implementation of FSMA. Please contact us if you have any questions.

3/ Letter from Food Laboratory Alliance et al. to Frank Yiannas, FDA Deputy Commissioner for Food Policy & Response (July 23, 2019) (Exhibit 1 to complaint).