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MEMORANDUM

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Re: Lawsuit Seeks to Compel FDA to Implement FSMA Traceability Provisions

Two consumer groups have sued the Food and Drug Administration (FDA) seeking to compel the agency to implement the traceability provisions in the FDA Food Safety Modernization Act (FSMA). Specifically, the plaintiffs want FDA to meet its obligation under FSMA to establish and publish a list of high-risk foods and engage in rulemaking setting forth additional traceability recordkeeping requirements for facilities that manufacture, process, pack, or hold those foods. 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 in 2012 after the agency did not meet the statutory deadlines for promulgating the seven major FSMA regulations. FDA settled the earlier lawsuit by establishing a schedule of deadlines for completion of the rulemakings, and FDA subsequently issued the regulations by the court-ordered deadlines. That lawsuit, however, did not address the statutory deadlines related to FSMA's traceability provisions, which are at issue in the present lawsuit.

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

FSMA Traceability Requirements

Section 204 of FSMA requires FDA to engage in several activities related to tracking and tracing food. 2/ In particular, as explained in more detail below, FSMA requires FDA to establish and publish a list of high-risk foods and engage in rulemaking setting forth additional traceability recordkeeping requirements related to such foods. 3/

1/ *Center for Food Safety v. Azar*, No. 3:18-cv-06299 (N.D. Cal. Oct. 14, 2018). The complaint is available at https://www.centerforfoodsafety.org/files/2018-10-15--doc-01--complaint_50519.pdf.

2/ 21 U.S.C. § 2223.

3/ Additionally, FSMA requires FDA to undertake pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to help prevent foodborne illness. Although FDA did not meet the associated statutory deadlines, FDA conducted these pilot programs and issued a report in March 2013. *See* Hogan Lovells memorandum dated March 14, 2013, *FDA Requests Comment on IFT Product Traceability Report Under FSMA*.

First, FSMA states that no later than 1 year after the law was enacted (i.e., by January 4, 2012), FDA must designate high-risk foods for which additional recordkeeping requirements "are appropriate and necessary to protect the public health." 4/ The designation for high-risk foods must be based on:

> (i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention (CDC);
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> (ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
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> (iii) the point in the manufacturing process of the food where contamination is most likely to occur;
>
> (iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
>
> (v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
>
> (vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

FDA may update the designation of high-risk foods, provided the agency provides notice of the update in the *Federal Register*.

Second, no later than 2 years after the law was enacted (i.e., by January 4, 2013), FDA was required to publish a notice of proposed rulemaking (i.e., proposed rule) to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold the foods FDA designates as high-risk foods. 5/ The purpose of these additional recordkeeping requirements is to facilitate the quick identification of recipients of food to prevent or mitigate a foodborne illness outbreak. The law includes several limitations on the content of this rulemaking. The new recordkeeping requirements would be in addition to the Bioterrorism Act's so-called "one up; one back" recordkeeping requirements in 21 CFR § 1.326 *et seq*.

Finally, when FDA finalizes this rulemaking the agency is required to publish on its website a list of the foods designated as high-risk foods.

FDA has not yet designated high-risk foods or issued a proposed rule for facilities that manufacture, process, pack, or hold those foods. In February 2014, FDA issued a *Federal Register* notice providing the agency's draft approach to identifying high-risk foods and soliciting comments and scientific data to help the agency refine the draft approach. 6/ In the notice, FDA recognizes the statutory deadline for its establishment of a list of high-risk foods, but notes that there are a number of topics on which public input would assist in effectively implementing the requirement. No further public actions related to traceability have been taken since that time.

4/ 21 U.S.C. § 2223(d)(2).
5/ 21 U.S.C. § 2223(d)(1).
6/ 79 Fed. Reg. 6596 (Feb. 4, 2014). *See* Hogan Lovells memorandum dated February 10, 2014, *FDA Requests Comments and Data on Designation of High-Risk Foods for Traceability Purposes Under FSMA*.

Summary of Complaint

The lawsuit alleges that FDA's failure to establish and publish a list of designated high-risk foods or to promulgate regulations establishing recordkeeping requirements for the facilities that handle those foods constitutes unlawfully withheld and unreasonably delayed action within the meaning of the Administrative Procedure Act (APA). 7/ The complaint explains that FDA's delay in promulgating the high-risk foods list and implementing the traceability recordkeeping regulations has put the plaintiffs' members' health and safety "in increased jeopardy, through the risk of contracting foodborne illness." According to the complaint, the groups' members and their families have fallen ill as a result of foodborne illness outbreaks, and they have paid "a price premium to make food from scratch and to buy organic produce and products to reduce the risk of contracting a foodborne illness."

According to the complaint, in the time that has elapsed since the statutory deadlines for these requirements, numerous foodborne outbreaks have occurred, which "may have been prevented or lessened if these FSMA measures were in place." The plaintiffs also argue, as presented in a May 2018 letter to FDA from a group of consumer groups, that retailers now have the technology (e.g., blockchain) to quickly identify the origin of food, which allows for enhanced traceability back to the source in a short amount of time. 8/ According to the plaintiffs, in light of these technological advances, "FDA can no longer shirk the mandatory actions required of it by Congress to designate high-risk foods and issue a rule for enhanced recordkeeping for those foods."

The two groups seek an order from the court declaring that FDA has violated FSMA and the APA by failing to meet its statutory deadlines and ordering FDA "to promulgate all FSMA regulations and complete all actions required under FSMA at issue in this case as soon as reasonably practicable, according to a Court-ordered timeline." The lawsuit was filed October 15, 2018, and the next step procedurally is for FDA to respond to the complaint.

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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.

7/ 5 U.S.C. § 555(b).

8/ Letter from Center for Foodborne Illness Research & Prevention, et al., to FDA Commissioner Scott Gottlieb, M.D. (May 24, 2018), available at https://cspinet.org/sites/default/files/attachment/Consumers%20letter%20to%20Comm.%20Gottlieb%20re%20traceability-5-24-18.pdf.