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**MEMORANDUM**

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**Re: Settlement Reached in Lawsuit to Compel FDA to Implement FSMA Traceability Provisions**

The U.S. Food and Drug Administration (FDA) reached a settlement with the two consumer groups that sued FDA in October 2018 to compel the agency to implement the traceability provisions in the FDA Food Safety Modernization Act (FSMA). The consent order, which was approved by the district court judge on June 11, 2019, establishes a timeline for FDA to 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/ This memorandum provides background on the FSMA traceability provisions and then summarizes the consent order. As explained in more detail below, FDA is committing to designate the list of high-risk foods and issue a proposed rule that would establish recordkeeping requirements for these foods by September 8, 2020, and then issue the final rule by November 7, 2022.

## FSMA Traceability Requirements

Section 204 of FSMA requires FDA to engage in several activities related to tracking and tracing food. 2/ In particular, 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/

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1/ *Center for Food Safety v. Azar*, No. 3:18-cv-06299 (N.D. Cal. Oct. 14, 2018). *See also* Hogan Lovells memorandum dated October 22, 2019, *Lawsuit Seeks to Compel FDA to Implement FSMA Traceability Provisions*.

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*. FDA also is required to establish a product tracing system within the agency to receive information that improves the capacity of the agency to effectively and rapidly track and trace food that is in the United States or offered for import. 21 U.S.C. § 2223(c). This provision has no statutory deadline.

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;
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> (iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
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> (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., a 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. 6/ The new recordkeeping requirements would be in addition to the Bioterrorism Act's so-called "one up; one back" recordkeeping requirements in 21 C.F.R. § 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

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4/ 21 U.S.C. § 2223(d)(2).
5/ 21 U.S.C. § 2223(d)(1).
6/ For example, the new requirements must: relate only to information that is reasonably available and appropriate; not prescribe specific technologies for the maintenance of records; not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business; not require a full pedigree, or a record of the complete previous distribution history of the food from the point of origin of such food; not require records of recipients of a food beyond the immediate subsequent recipient of such food; and not require product tracking to the case level.

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. 7/ 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.

CFS and CEH filed the lawsuit against FDA in October 2018, alleging 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). They requested 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 implement the traceability provisions by court-ordered deadlines.

**Consent Order**

FDA, CFS, and CEH have agreed to the following timeline for FDA's implementation of the traceability provisions.

- **Creation of High-Risk Foods List**: FDA will designate the list of high-risk foods required by FSMA Section 204(d)(2)(A) by September 8, 2020.

- **Rulemaking for Recordkeeping Requirements**: FDA will issue a proposed rule to establish recordkeeping requirements for food designated as high-risk, as required by FSMA Section 204(d)(1), by September 8, 2020. FDA will issue the final rule by November 7, 2022.

- **Publication of High-Risk Foods List:** FDA must publish on its website the list of high-risk foods, as required by FSMA Section 204(d)(2)(B), upon publication of the final rule in the *Federal Register*.

As applicable, the dates listed above are the dates by which FDA is required to submit the documents to the Office of the Federal Register for publication, rather than the dates by which the documents must be published.

The consent order also lays out procedures for FDA to seek an extension from the court of the above timelines in the event that the agency believes an extension is necessary and the parties are unable to reach an agreement regarding extension of the deadlines. The procedures require FDA to show good cause and/or exceptional circumstances warranting a delay.

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

7/ 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*.