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MEMORANDUM

From: Joseph A. Levitt
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Date: September 18, 2017

Re: FSMA Implementation Update – Produce Safety and Preventive Controls Developments

There have been several notable recent developments involving FSMA implementation. Most significantly, FDA proposed to extend the compliance dates for the agricultural water provisions of the Produce Safety rule and announced it will delay the start of Produce Safety rule inspections until spring 2019. Additionally, FDA has issued another chapter of its Preventive Controls for Human Foods (PCHF) draft guidance, which addresses the use of heat treatment process preventive controls. In addition to summarizing these developments, this memorandum also provides a reminder that the next round of FSMA compliance dates for the Preventive Controls rules is September 18, 2017.

FDA Extends Agricultural Water Compliance Dates and Delays Produce Safety Inspections

FDA recently issued a Proposed Rule to extend and harmonize the compliance dates for the agricultural water provisions in the Produce Safety rule (for produce other than sprouts). ^{1/} The agency proposed the following revised and aligned compliance dates:

| Size of Covered Farm | Proposed New Compliance Date |
|-----------------------|------------------------------|
| Very small businesses | January 26, 2024 |
| Small businesses | January 26, 2023 |
| All other businesses | January 26, 2022 |

The Proposed Rule explains FDA is taking this action to “address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies.” FDA requests comments on whether this change to the compliance dates and their structure would be helpful. Comments are due November 13, 2017.

The proposed extension is only for compliance with the agricultural water provisions of the rule. In addition, the proposed rule does not address the underlying requirements in subpart E regarding the agricultural water standards. However, FDA will use the additional time before the compliance dates to consider approaches to address issues that have been raised with the requirements under the rule. For example, FDA plans to engage with stakeholders on issues related to compliance,

^{1/} 82 Fed. Reg. 42963 (Sept. 13, 2017). Note that this extension would not apply for sprouts.

including holding a summit on agricultural water early next year. FDA also has identified eight additional water testing methods it has determined are equivalent to Method 1603, which was incorporated by reference into the Produce Safety rule for use in agricultural water testing. ^{2/} FDA intends to add other methods to its list as it identifies them.

Significantly, FDA Commissioner Scott Gottlieb also recently announced that FDA will not begin inspections for compliance with the non-water requirements of the Produce Safety rule until spring 2019 (except for sprouts). ^{3/} FDA is taking this action because of input from farmers and state regulators that “more time is necessary to ensure farmers have the training and information needed to comply and that states establish strong produce regulatory programs before inspections begin.” ^{4/} The additional year will be used to focus on issuing guidance, providing training and technical assistance, and improving information for work planning such as developing farm inventories.

FDA Issues Draft Guidance on Heat Treatment Process Preventive Controls

FDA currently is developing a multi-chapter guidance document on the Preventive Controls for Human Food (PCHF) rule. ^{5/} This month it released the sixth draft chapter, which focuses on the use of heat treatment as a process control. ^{6/} The draft guidance addresses how to establish and implement a heat treatment (e.g., baking or cooking) as a process control for bacterial pathogens, including the design and validation of a heat treatment; monitoring, corrective action, and validation procedures; and records maintenance. To illustrate these points, the guidance discusses the hypothetical heat treatments used for processing cookies, soup, and salsa. Comments on the heat treatment chapter of the draft guidance are due February 27, 2018.

FDA will continue to release incrementally the additional nine chapters of the guidance. Forthcoming chapters will address time/temperature control, formulation, dehydration/drying, sanitation controls, food allergen controls, preventive controls for chemical hazards, preventive controls for physical hazards, recall plans, and supply-chain programs.

Next Round of Preventive Controls Compliance Deadlines Arrives This Month

The next compliance deadline for the Preventive Controls rules arrives on September 18, 2017. This is the date when a “small business” with fewer than 500 full-time equivalent (FTE) employees must comply with the Preventive Controls for Human Food regulation. This also is the compliance date for larger businesses (with more than 500 FTEs) to comply with the preventive controls

^{2/} The equivalent water testing methodologies are available at <https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM575255.pdf>.

^{3/} FDA Commissioner Addresses State Agriculture Commissioners; Announces New Steps to Enhance Collaboration with States and Ensure Farmers Are Prepared for FSMA, available at <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm575532.htm>.

^{4/} Dr. Scott Gottlieb’s Speech to the 2017 NASDA Annual Meeting, available at <https://www.fda.gov/NewsEvents/Speeches/ucm575499.htm>.

^{5/} Hogan Lovells Memorandum, *FDA Releases Series of Draft FSMA Guidance Documents* (Sept. 7, 2016).

^{6/} “Use of Heat Treatments as a Process Control,” *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (Aug. 2017), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM573227.pdf>; 82 Fed. Reg. 41364 (Aug. 31, 2017).

requirements under the Preventive Controls for Animal Food rule and for small businesses to comply with the current Good Manufacturing Practices (cGMP) requirements under that rule. 7/

Bear in mind, however, that there are a few exceptions to the September 18, 2017 compliance date due to extensions issued by FDA. 8/ For example, facilities solely engaged in packing and/or holding raw agricultural commodities that are produce and/or nut hulls and shells are not required to comply with the Preventive Controls rules until the applicable Produce Safety rule compliance date for their size business (e.g., January 26, 2018 for Preventive Controls for Human Food for a company with more than 500 full-time equivalent (FTE) employees).

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.

7/ FDA has announced that inspections under the Preventive Controls for Animal Food rule will focus on only cGMPs (rather than Preventive Controls) until the fall of 2018. See Hogan Lovells Memorandum, *FSMA Implementation Update* (Aug. 16, 2017).

8/ 81 Fed. Reg. 57784 (Aug. 24, 2016); see Hogan Lovells Memorandum, *FDA Extends Several FSMA Compliance Dates* (Sept. 7, 2016).