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MEMORANDUM

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Re: **FSMA Implementation Update**

There have been several recent developments regarding implementation of the FDA Food Safety Modernization Act (FSMA) of interest to the food industry. This memorandum summarizes the following topics:

- Delayed start date for inspections for compliance with the preventive controls requirements under the Preventive Controls for Animal Food (PCAF) rule and under the Foreign Supplier Verification Programs (FSVP) rule for animal food importers;
- Guidance for low-acid canned food (LACF), seafood, and juice manufacturers regarding compliance and exemptions under FSMA;
- Updated domestic and foreign reinspection fee rates for fiscal year (FY) 2018;
- Release of new Food Safety Plan Builder software to assist with development of food safety plans; and,
- Clarification regarding the definition of "retail food establishment" for purposes of the waiver from requirements under the Sanitary Transportation of Human and Animal Food rule.

1. Delayed Start Date for Preventive Controls and FSVP Inspections for Animal Food

Larger animal food companies (i.e., with more than 500 full-time equivalent employees) must comply with preventive controls requirements under the PCAF rule by September 18, 2017. 1/ These facilities were already required to comply with Current Good Manufacturing Practice (cGMP) requirements for animal food by September 2016. The cGMP requirements take effect in September 2017 for small animal food companies (with fewer than 500 full-time equivalent employees), with the preventive controls requirements not effective until September 2018 for these businesses.

1/ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, Final Rule, 80 Fed. Reg. 56169 (Sept. 17, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf.

In light of this pending compliance date, FDA recently announced that while large animal food facilities are required to meet the preventive controls requirements as of September 18, **FDA will not be conducting routine regulatory inspections to ensure compliance with the preventive controls requirements for animal food until the fall of 2018.** Additionally, because FDA is not yet beginning inspections of animal food facilities to ensure compliance with preventive control requirements, the agency will also not begin Foreign Supplier Verification Program (FSVP) inspections for animal food importers until the fall of 2018. This way, the start of the FSVP inspections for these importers will be aligned with the start of preventive controls inspections for animal food.

On August 10, FDA released a Q&A format document to provide insight on the upcoming compliance dates and what facilities can expect in terms of education, training, and compliance with the requirements.2/ FDA stated that the delay in inspections for preventive controls for animal food is appropriate because industry needs more time and technical assistance to fully understand the requirements. The agency is trying to give facilities the opportunity to further develop their plans and ensure their systems are operating correctly as guidance from FDA and other resources are developed and implemented.

Firms should be aware that cGMP inspections are not being postponed. Although FDA will not be inspecting for compliance with preventive controls requirements, there will be an increased level of oversight of cGMPs for animal food with more routine inspections. This is because, as of September 18, 2017, both large and small facilities will be required to meet the animal food cGMP requirements. Industry also should keep in mind that if FDA finds a problem at a facility that has reached its preventive controls compliance date, it will be looking at the facility's food safety plan to see what controls they have outlined.

Note that this announcement does not affect companies that are regulated under only the Preventive Controls for Human Food rule. FDA is actively inspecting for compliance with the preventive controls requirements for human food facilities.

2. Guidance on LACF/Seafood/Juice Compliance-Exemptions

On August 7, FDA published three separate guidance documents to assist producers of low-acid canned foods, juice, and seafood understand which parts of the FSMA rules apply to each industry, and how the FSMA rules may affect their operations. 3/

2/ What to Expect With the Next Compliance Dates for the FSMA Preventive Controls for Animal Foods Rule, https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm570439.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

3/ Guidance for Industry: Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act, https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569792.pdf.
Guidance for Industry: Juice HACCP and the FDA Food Safety Modernization Act, https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569777.pdf.
Guidance for Industry: Seafood HACCP and the FDA Food Safety Modernization Act, https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569798.pdf.

FSMA recognizes that FDA has previously-established regulations that are specific to seafood, juice, and LACF operations, and as such these foods are subject to certain exemptions within the regulations. Even so, there are some requirements within FSMA that apply to processors of seafood, juice, and LACF products.

The three new guidance documents specifically address each type of operation. The guidances are intended to help industry identify applicable exemptions, as well as identify which cGMP, preventive controls, FSVP, Produce Safety, Intentional Adulteration, and Sanitary Transportation regulations apply, if any, for these foods. The guidances address the specific exemptions under the Final Rules, and then present in a Question / Answer format information about the industry in connection with the FSMA regulations (as applicable). While the guidances do not necessarily proffer novel information, they are useful tools for industry to understand how the regulations under FSMA do or do not apply.

3. Updated Reinspection Fee Rates

On August 2, FDA announced the fiscal year (FY) 2018 fee rates for certain domestic and foreign facility reinspections, failure to comply with a recall order, and importer reinspections that are authorized FSMA. 4/ These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018. Note that FDA currently is not invoicing firms or facilities while it works to resolve issues concerning fee adjustments for small businesses and issues involved in applying reinspection fees for imports.

The time spent on each reinspection, or in taking action in response to a firm's failure to comply with a recall order, will be billed at the hourly rate shown in the table below:

Fee Category Fee Rates for FY 2018	Fee Category Fee Rates for FY 2018
Hourly rate if domestic travel is required $248	$248
Hourly rate if foreign travel is required $285	$285

The fee for foreign work is unchanged from FY 2017, while the domestic hourly fee increased from $221. 5/ Fees are to be paid by the responsible party for each domestic facility or by the U.S. agent for each foreign facility.

4. Food Safety Plan Builder (FSPB)

On August 11, FDA released the "Food Safety Plan Builder" (FSPB) Version 1, a tool designed to assist owners/operators of food facilities with the development of food safety plans that are

4/ Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2018, Notice, 82 Fed. Reg. 35954 (Aug. 2, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-08-02/pdf/2017-16184.pdf.

5/ *See* Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2017, Notice, 81 Fed. Reg. 50525 (Aug. 1, 2016) https://www.gpo.gov/fdsys/pkg/FR-2016-08-01/pdf/2016-18089.pdf.

specific to their facilities and meet the requirements of the Preventive Controls for Human Food rule. 6/

FDA indicates that use of this tool is strictly optional, and although Version 1 is consistent with FDA's existing guidance and regulations, use of the FSPB by owners and operators of food facilities does not guarantee that their food safety plan, preventive controls, cGMPs, or other food safety procedures are approved by FDA or comply with FDA requirements.

The Food Safety Plan Builder guides the user through all potential parts of a food safety plan, so users should understand that not all sections will be relevant to their facilities. The resource page includes links to download the software, training videos, and individual chapters for each of the different aspects of a food safety plan. 7/

5. Sanitary Transportation of Human and Animal Food Rule Waiver for Retail Food Establishments

On August 14, FDA released a guidance document to provide clarification on the scope of the waiver for food establishments that provide food directly to consumers from the requirements of the Sanitary Transportation of Human and Animal Food Rule. 8/

As background, in April 2017, FDA announced three waivers from the Sanitary Food Transportation rule for businesses whose transportation operations are already subject to existing regulatory controls at the federal, state or local levels, including a waiver for certain requirements for restaurants, retail food establishments, and nonprofit food establishments. 9/ Following publication of the waivers, FDA received questions regarding the scope of the term "retail food establishment," and whether it also applies to businesses that sell animal food, because the definition of retail food establishment can include establishments that sell food for human or animal consumption.

The guidance clarifies that the retail food establishment waiver applies to establishments that are permitted or otherwise authorized by the regulatory authority to sell human food. 10/ Further, it also clarifies that the establishments that are permitted or otherwise authorized to sell

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6/ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, Final Rule, 80 Fed. Reg. 55907 (Sept. 17, 2015) https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf.

7/ FDA Food Safety Plan Builder reference webpage, https://www.fda.gov/food/guidanceregulation/fsma/ucm539791.htm.

8/ FDA Guidance for Industry, Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule (Aug. 2017) https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM571341.pdf.

9/ Waivers From Requirements of the Sanitary Transportation of Human and Animal Food Rule, Notice, 82 Fed. Reg. 16733 (Apr. 6, 2017) https://www.gpo.gov/fdsys/pkg/FR-2017-04-06/pdf/2017-06854.pdf.

10/ FDA stated that for the purpose of establishing the scope of the waiver, it intended to define "food establishment" using the definition set forth in the 2009 edition of the FDA's Food Code, which includes only operations that provide food for human consumption. *See* 79 Fed. Reg. 705, 7030 (Feb. 5, 2014) https://www.gpo.gov/fdsys/pkg/FR-2014-02-05/pdf/2014-02188.pdf.

human food, that sell both human and animal food, also fall under the retail food establishment waiver. However, consistent with the principle that the waiver only applies to establishments that are permitted to sell human food, the waiver does not extend to establishments that only sell food for animals and do not sell food for humans.

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We will continue to monitor these and other developments related to FSMA implementation. Please contact us if you have any questions.