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MEMORANDUM

From: Joseph A. Levitt
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Date: March 26, 2018

Re: **FSMA Implementation Update (March 2018)**

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

- Guidance on application of the Foreign Supplier Verification Programs (FSVP) regulation to the importation of certain live animals;
- Draft Guidance on the definition of "small business" for purposes of the Preventive Controls for Human Food (PCHF) and Preventive Controls for Animal Food (PCAF) regulations;
- A letter to the winegrape and hops growing industries regarding possible modifications to written assurances in the Produce Safety Rule; and
- A report from the Government Accountability Office (GAO) scrutinizing FDA's progress and implementation of key food safety-related activities.

Also, as a reminder, March 19, 2018 was the compliance date for supplier verification under the PCHF (Subpart G) and FSVP regulations when a supplier is a "small business" required to comply with the PCHF regulation. 1/ Additionally, April 6, 2018 is the compliance date for small businesses for the Sanitary Food Transportation regulation. 2/

1. Guidance Announcing Enforcement Discretion from FSVP for Importation of Certain Live Animals

FDA has issued Guidance entitled *Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals*. 3/ This Guidance (which was issued in final form with

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1/ March 19, 2018 also was the compliance date for an importer of animal food if (1) their large business foreign supplier is subject to the Preventive Controls requirements in the PCAF regulation, but not the current Good Manufacturing Practice (cGMP) requirements; or (2) their small business foreign supplier is subject to the cGMP requirements under the PCAF regulation.

2/ Under the Sanitary Food Transportation regulation, "small business" means "a business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receiver, this term would mean a business subject to [21 CFR] § 1.900(a) having less than $27,500,000 in annual receipts." 21 CFR § 1.904.

3/ The Final Guidance is available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM601214.pdf.

no preceding draft) explains that FDA will exercise enforcement discretion for compliance with FSVP for importers of live animals that are required to be slaughtered and processed at U.S. Department of Agriculture (USDA)-regulated establishments subject to USDA-administered hazard analysis and critical control point (HACCP) requirements. However, as explained below, this enforcement discretion does not apply when the animals will be processed at FDA-regulated establishments.

The Guidance explains that FDA regulates live animals imported for use as food, and these imports are therefore covered by the FSVP regulation. However, most live animals imported for use as food (including cattle, poultry, and swine) are slaughtered under the regulatory requirements put in place by the USDA's Food Safety and Inspection Service (FSIS), and are processed at facilities subject to USDA HACCP requirements. The Guidance explains that FSIS and USDA's Animal and Plant Health Inspection Service (APHIS) have comprehensive regulatory requirements, including HACCP requirements, which control food safety hazards in live animals that must be slaughtered and processed in official USDA establishments (those requiring a grant of inspection to operate).

Accordingly, the Guidance explains:

> In light of the role of another Federal agency with regard to these animals, FDA intends to exercise enforcement discretion with respect to the FSVP regulation for importers of live animals that are imported for slaughter and processing at USDA-regulated establishments subject to USDA-administered HACCP requirements, or imported for slaughter and processing under state requirements that are at least equivalent to the requirements for USDA-regulated establishments, including designated feeder animals. 4/ This means that we will not expect FSVP importers of live animals that are slaughtered and processed at USDA-inspected establishments subject to USDA-administered HACCP requirements (or state-inspected establishments subject to equivalent requirements) to meet any of the FSVP requirements.

FDA explains that this intent to exercise this enforcement discretion is consistent with the exemption from the FSVP requirements for foods that are under USDA jurisdiction.

Notably, this enforcement discretion does not apply to importers of live animals for food use that fall under FDA jurisdiction (e.g., farmed bison, farmed wild boar, and elk). These animals are not processed at USDA-regulated slaughter and processing establishments under HACCP requirements (or state-inspected establishments with equivalent requirements). FDA states that an importer of such animals would be subject to FSVP and would need to conduct foreign supplier verification with respect to such animals if the importer determined there were drug residues or other hazards requiring supplier control.

FDA also notes that it will consider revising its intent to exercise enforcement discretion if, for example, there are changes to the information upon which its intent to exercise enforcement discretion is based or if new information becomes available regarding safety concerns associated with the importation of these live animals. Importers are directed to use the Affirmation of Compliance code "FSX" at entry to signal that a food is not subject to FSVP because FDA is exercising enforcement discretion.

4/ By "feeder animals" FDA means animals going to feedlots for finishing before slaughter.

2. Draft Guidance on "Small Business" Definition for PCHF and PCAF Rules

FDA has issued Draft Guidance entitled *Determining the Number of Employees for Purposes of the "Small Business" Definition in Parts 117 and 507*. 5/ First, small businesses are exempt from the preventive controls requirements in the PCHF and PCAF rules if they are only engaged in specified low-risk activity/food combinations specified in the regulations. Second, small businesses have later compliance dates than large businesses and large businesses sourcing from small businesses have later compliance dates for their own supplier verification programs. 6/

The PCHF and PCAF regulations define "small business" as "a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees," which is the number specified by the Small Business Administration. 7/ The draft guidance focuses on explaining this definition. For example, FDA emphasizes that this definition includes all employees at the business company-wide and is not limited to the employees at a particular facility. The guidance also addresses which employees to count, the meaning of "full-time equivalent employee" (FTE), how to determine the number of FTEs, and how to determine the extent of a business (e.g., affiliates and subsidiaries). FDA also provides a number of detailed examples.

Comments on the draft guidance are requested by May 21, 2018.

3. FDA Discusses Commercial Processing Exemption in Letter to Winegrape and Hops Growers

FDA recently posted a letter sent to the winegrape and hops growing industries regarding their concerns about winegrapes and hops being excluded from the rarely consumed raw list codified in 21 CFR § 112.12 of the Produce Safety rule. 8/ Produce can be exempt from the Produce Safety rule either because it is on the rarely consumed raw list or because it falls under the commercial processing exemption. Rather than addressing these industries' concerns through modifications to the rarely consumed raw list, FDA appears interested in addressing the burdens posed by the recordkeeping requirements for the commercial processing exemption (i.e., written disclosures and written assurances). Notably, the letter provides a window in to what future written disclosure and written assurances requirements may look like.

Importantly, FDA's January 4, 2018 announcement of enforcement discretion for written assurances in the PCHF, PCAF, Produce Safety, and FSVP rules said the enforcement discretion will only remain in place until FDA completes a planned future rulemaking on this issue. In the letter to the winegrape and hops growing industries, FDA states: "We are exploring options to allow for exemption from the records requirement as part of the commercial processing exemption for certain commodities. We will likely need to engage in rulemaking to expand the exemption. We are also

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5/ The Draft Guidance is available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM600967.pdf.

6/ While the compliance dates have already passed for small businesses under the PCAF rule and for supplier verification from small businesses under the PCHF and FSVP rules, the dates have not yet all passed in connection with the PCAF rule. Small businesses currently are required to comply with the cGMP requirements under the PCAF rule, but have until September 17, 2018 to comply with the preventive control requirements under the PCAF rule. Correspondingly, there are upcoming compliances dates for FSVP related to sourcing from these suppliers.

7/ 21 CFR § 117.3; 21 CFR § 507.3.

8/ The letter is available at: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM601347.pdf.

considering streamlining and reducing the records requirements for those growers who have annual contracts with commercial processors." Therefore, FDA's letter suggests that the written assurances provisions may be reinstated in some form, at least in the Produce Safety rule.

4. GAO Report Scrutinizes FDA's Benchmarks for Achieving Food Safety Goals

Finally, the GAO recently issued a report entitled *Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities*. 9/ The report notes that the FDA has undertaken significant efforts on food safety-related activities since the enactment of FSMA, dedicating at least $1 billion annually to these activities in fiscal years 2011 through 2016. However, the GAO report ultimately finds that the agency does not institute adequate measures to assess progress toward its goals.

Specifically, the GAO raises several concerns regarding FDA's implementation of FSMA and its progress toward achieving food safety-related strategic goals, including that (1) it does not consistently document its decisions, causing inconsistency and a lack of transparency; (2) the agency does not develop performance measures (including both targets and time frames), making it difficult to assess progress; and (3) time frames for longer-term activities are unclear. In order to address these issues, the GAO offers recommendations to the FDA, including implementing a system to document decisions, developing adequate performance measures, and setting a longer-term implementation plan.

FDA Commissioner Scott Gottlieb released a statement in response to the report. 10/ The Commissioner focused on the positive aspects of the report, noting that it finds that "the FDA continues to make significant progress in implementing new and enhanced programs aimed at protecting our food supply and promoting healthier food choices." As for the GAO report's recommendations, Commissioner Gottlieb says he agrees on the importance of transparency and clear implementation goals. He says that the FDA will continue to work to modernize its food safety metrics by "putting in place outcome-based performance measures that can more accurately reflect the public health impact of the agency's actions."

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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.

9/ The GAO report is available at https://www.gao.gov/assets/690/689796.pdf. The report also discusses FDA's progress on nutrition-related activities, which are outside of the scope of this memorandum.

10/ The statement is available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm599398.htm.