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MEMORANDUM

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Re: **FSMA Implementation Update: Recent Developments Affecting Imports, Sanitary Food Transportation, Produce Safety, and Very Small Businesses**

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

- Regarding imports:
  - FDA's recognition of Australia's food safety system as comparable to the United States, which allows for modified Foreign Supplier Verification Programs (FSVP) requirements of certain foods imported from Australia;
  - Information from FDA to importers about key things they need to know about compliance with the FSVP rule and what to expect during upcoming inspections; and
  - Launch of a website where organizations can apply for recognition as a third-party accreditation body.
- Information from FDA on the agency's implementation of the Sanitary Transportation of Human and Animal Food (Sanitary Food Transportation) rule;
- FDA's plans to extend the compliance dates for the agricultural water requirements of the Produce Safety regulation; and
- Inflation-adjusted values applicable to several very small business-related definitions used in the FSMA rules.

1. Import-Related Developments

A. U.S. – Australia Comparability Determination

FDA has entered into an arrangement with the Australian Department of Agriculture and Water Resources under which the two countries recognize each other's food safety systems as

comparable. 1/ FDA's system recognition process involves reviewing a foreign country's domestic food safety regulatory system to determine if it has legal authorities and regulatory tools that provide a food safety system comparable to that of the United States. Australia is the third country that FDA has found to have a comparable food safety system; FDA made such a determination for New Zealand in 2012 and Canada in 2016. 2/

This recognition allows for importers of food from Australia that is not intended for further manufacturing/processing (including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption) to follow modified FSVP requirements, so long as the food is within the scope of the arrangement. 3/ Foods excluded from the arrangement are: meat (except game meat); poultry; processed egg products; farmed catfish and catfish products; U.S. Grade A milk and Grade A milk products and raw milk cheese; raw bivalve molluscan shellfish; dietary supplements; and natural health products.

B. FDA Shares Compliance-Focused Q&A on FSVP Rule

FDA has published a web resource entitled *FSVP: What Do Importers Need to Know*, which provides questions and answers from Sharon Mayl, Senior Advisor for Policy in the Office of Foods and Veterinary Medicine, on compliance-related FSVP information for importers. 4/ Ms. Mayl confirms that FDA plans to take the same "educate while we regulate" approach that it took for compliance with the Preventive Controls regulations in September 2016. Under this approach, importers can expect interactive FDA inspections "with opportunities to explain how their programs meet [FDA's] requirements and how they will take corrective actions if [FDA] observe[s] deficiencies." She states that in most cases, FDA will provide importers with an opportunity to correct deficiencies, except where problems pose a danger to health or reflect intentional disregard for legal responsibilities. When corrective actions are required, she says importers should communicate clearly to FDA what actions they will take and when the corrections will be completed.

Additionally, Ms. Mayl advises on the use of third-party audits as a verification activity. In response to the question: "I already audit my supplier. Can I use that audit as a verification activity?," she responds that importers need to make sure that the audits they use meet the requirements in the rule – namely that the audit considers the FDA food safety requirements that apply, and that the auditor is qualified to perform the audit (e.g., education, training, experience). She acknowledges that FDA is: "[A]ware of several organizations, such as the USDA's Agricultural Marketing Service (AMS) and the Global Food Safety Initiative (GFSI), that are working to ensure their audits meet our requirements." She cautions, however, that FDA "encourage[s] all importers to ensure the scope of the audits they currently use consider all applicable FDA food safety regulations, including the Preventive Controls and Produce Safety rules if they apply to their supplier." In addition, she says importers "should ensure that the auditors performing the audits are qualified auditors in accordance with the FSVP rule."

1/ *Food Safety Systems Recognition Arrangement Between the Australian Department of Agriculture and Water Resources and the FDA of the United States of America*, *available at* https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm555986.htm.

2/ FDA is now working with the European Union to assess the comparability of their systems.

3/ 21 CFR § 1.513. The rule does not, however, provide for an exemption from FSVP.

4/ *FSVP: What Do Importers Need to Know?* (May 26, 2017), *available at* https://www.fda.gov:80/FDAgov/Food/GuidanceRegulation/FSMA/ucm560689.htm.

C. FDA Begins Accepting Applications for Accreditation Body Recognition Under Third-Party Certification Rule

As part of its implementation of its voluntary Accreditation of Third-Party Certification Bodies regulation, 5/ FDA has announced that organizations can now apply for recognition as accreditation bodies. 6/ This is an important step for implementation of the rule. As background, FDA will recognize "accreditation bodies" that will have the responsibility of accrediting third-party "certification bodies" (i.e., third-party auditors). The certification bodies will conduct audits and issue certifications of foreign food facilities. Such certifications will be used for two purposes: (1) to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review and entry of food; and (2) in the rare and specific circumstances when FDA can require that an imported product be certified to prevent a potentially harmful food from entering the United States. FDA also has released a new fact sheet providing key information regarding the Accredited Third-Party Certification Program. 7/

Foreign governments and agencies, as well as private third parties, are eligible to apply for recognition. The accreditation process includes a web-based application and an application fee of $35,100 for applications submitted in fiscal year 2017. 8/ Organizations that wish to become an accreditation body or a certification body must meet the eligibility requirements for the program, including:

- Possessing and demonstrating authority to assess a third-party certification body for accreditation and to conduct site audits and review records;
- Possessing and demonstrating capacity and competency, including having adequate (1) finances for operation, (2) staff with the knowledge, skills, and experience to perform effectively, and (3) resources and equipment necessary for audits and testing;
- Having a written program to monitor quality assurance;
- Having written measures to protect against conflicts of interest; and
- Having written procedures to establish, control, and retain records.

FDA will post a notification on the Accredited Third-Party Certification Program webpage for each accreditation body it recognizes. Accreditation bodies may begin to audit certification bodies to issue certifications under this program once they receive recognition from FDA. FDA also plans to provide information about each certification body that is accredited.

2. Implementation of Sanitary Food Transportation Rule

The first compliance date for the Sanitary Food Transportation rule was April 6, 2017. 9/ FDA recently issued a fact sheet on the implementation of the rule, which emphasizes the agency also intends to follow its "educate before and while we regulate" approach for this rule by focusing on

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5/ 80 Fed. Reg. 74750 (Nov. 27, 2015).
6/ *FDA Constituent Update: FDA Launches Accredited Third-Party Certification Site*, *available at*: https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm563215.htm.
7/ *Key Facts about the Accredited Third-Party Certification Program*, *available at*: https://www.fda.gov/downloads/Food/GuidanceRegulation/ImportsExports/Importing/UCM564000.pdf.
8/ 81 Fed. Reg. 90363 (Dec. 14, 2016). This notice also include FDA's estimates of other fees under this program that will be assessed once accreditation bodies are recognized.
9/ *See* 21 C.F.R. § 1.900 et. seq.

supporting compliance through education in the initial months of implementation. 10/ FDA stated that it expects to begin inspections later this year. The first round of inspections will be "to assess the industry's level of readiness and, if deficiencies are found, to provide firms with the information they need to achieve compliance." FDA is currently training investigators to inspect firms for compliance with the rule.

FDA has also explained that it is developing a free training module for carriers that will be available in the next few months. FDA acknowledged that until the agency's training module is available, carriers may have difficulty acquiring training and providing documentation of such training. FDA encourages shippers to work with carriers to ensure carriers are aware of the requirements of the rule and that food is transported in a safe and sanitary manner. FDA also intends to publish a small entity compliance guide for the Sanitary Food Transportation rule later this year.

3. Compliance Date Extension for Agricultural Water Requirements Under Produce Safety Rule

FDA has announced that it intends to extend the compliance dates for the agricultural water requirements (other than for sprouts) of the Produce Safety regulation. 11/ The original compliance dates for these requirements were set to begin in January 2020 (but certain sampling would have had to begin sooner). FDA did not state how long it will extend the compliance dates, as "the length of the extension is under consideration." FDA previously announced in March 2017 that it was exploring ways to simplify the microbial quality and testing requirements for agricultural water after receiving feedback from stakeholders that some of the requirements may be too complex to understand, translate, and implement. FDA explained in its recent extension announcement that it will use the extended time period to work with stakeholders as it considers the best approach to address their concerns while still protecting public health.

4. Updates to Inflation-Adjusted Cut Offs for Very Small Businesses

FDA recently posted the inflation-adjusted values for the monetary thresholds used under various very-small-business-related definitions in the FSMA rules (e.g., the annual sales threshold in the definition of "very small business" under Preventive Controls). 12/ These values are important because they can affect which legal requirements apply to a particular facility or farm, as well as the applicable compliance deadline. Likewise, they can affect obligations for recipients of foods from these facilities and farms under the supplier verification rules and the corresponding deadline for conducting that verification.

To adjust the baseline values established in the regulations for inflation, FDA uses the Federal calculation for the Gross Domestic Product price deflator, provided by the Bureau of Economic Analysis. 13/ FDA intends to update these values at the end of March each year. Below we provide a table with the average three-year inflation-adjusted values for the FSMA rules, which are the

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10/ *See* Sanitary Food Transportation Rule: Implementation, *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM553930.pdf.
11/ *FDA Intends to Extend Compliance Dates for Agricultural Water Standards*, *available at* https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm561844.htm.
12/ *FSMA Inflation Adjusted Cut Offs*, *available at* https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm.
13/ 80 Fed. Reg. 55908, 56075 (Sept. 17, 2015).

values that need to be taken account of when determining whether an entity meets the very-small-business-related definitions under the various FSMA rules as of 2017.

By way of example, the Preventive Controls for Human Food definition of "very small business" includes a threshold of an average of "less than $1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g., held for a fee)" (emphasis added). 14/ Using the inflation-adjusted values provided by FDA, in 2017 a facility's average annual income now would need to be below $1,065,291 to qualify as a "very small business."

FSMA Inflation-Adjusted Cut Off Values

Regulation and Definition	Baseline Value for Cut-offs (2011)	Average 3 Year Value for 2014 - 2016
Preventive Controls for Human Food: "Very Small Business"	$1,000,000	$1,065,291
Preventive Controls for Animal Food: "Very Small Business"	$2,500,000	$2,663,227
Produce Safety Rule: "Qualified Exemption"	$500,000	$532,645
Produce Safety Rule: "Not Covered Farm"	$25,000	$26,632
Foreign Supplier Verification Programs: Human Food: "Very Small Importer"	$1,000,000	$1,065,291
Foreign Supplier Verification Programs: Animal Food: "Very Small Importer"	$2,500,000	$2,663,227
Sanitary Transportation of Human and Animal Food: "Non-covered Business"	$500,000	$532,645
Intentional Adulteration: "Very Small Business"	$10,000,000	$10,652,906

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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.

14/ 21 C.F.R. § 117.3.