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MEMORANDUM

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Re: FDA Begins Accepting VQIP Applications and Recognizes First Accreditation Body under FSMA's Accredited Third-Party Certification Program

The U.S. Food and Drug Administration (FDA) has taken two important steps to launch the Voluntary Qualified Importer Program (VQIP) under the FDA Food Safety Modernization Act (FSMA). 1/ First, FDA has started accepting applications for participation in VQIP, a voluntary, fee-based program which offers expedited review and entry of human and animal food into the United States. Second, FDA has recognized the first accreditation body under the voluntary Accredited Third-Party Certification Program created by FSMA, a step needed to implement VQIP. This memorandum discusses both developments.

VQIP

FDA announced on January 31, 2018, that it has started accepting applications for participation in VQIP. Participants in VQIP receive expedited review and entry of food imports, with FDA's examination and sampling of VQIP foods limited to "for cause" situations where FDA suspects a potential risk to the public. 2/ In addition, when FDA intends to examine or sample a VQIP food, the examination or sampling will, to the extent possible, be at the food's destination or another location chosen by the importer. FDA also will expedite any laboratory processing samples of VQIP food. An additional benefit of participation in the program will be the ability for FDA to focus resources on non-VQIP importers that present greater potential risk to public health. As described further below, VQIP is a voluntary, fee-for-service program.

FDA has established detailed eligibility criteria for VQIP. In particular, VQIP foods must be produced in a foreign facility or farm that is certified by an auditor accredited through FDA's Accredited Third-Party Certification Program (discussed below). In addition, importers should have at least a three-year history of importing food into the United States and be in compliance with supplier verification and other responsibilities under the Foreign Supplier Verification Programs (FSVP) rule. VQIP participation also requires the development and implementation of a Quality Assurance Program

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1/ FDA Takes Important New Steps to Strengthen Oversight of Food Imports (Jan. 31, 2018), available at https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm594524.htm.

2/ Outlining the Benefits of the Voluntary Qualified Importer Program: A Conversation with Doriliz De Leon and Amelia Tetterton (Jan. 2, 2018), available at https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm590803.htm.

(QAP), which includes written policies and procedures regarding safety and security.

FDA plans on assessing up to 200 applications in the first year of the program, depending on resource availability, and it will review applications on a first-come, first-served basis. The anticipated fee is $16,400 annually, though the final cost has not yet been finalized. There also will be fees related to obtaining appropriate third-party certifications for the foreign facilities.

Accredited Third-Party Certification Program

FDA also announced that the ANSI-ASQ National Accreditation Board (ANAB) is the first organization to be recognized under FDA's voluntary Accredited Third-Party Certification Program. 3/ ANAB has been recognized for a five-year term. According to FDA, ANAB was recognized because it met the applicable FDA requirements, validated through application review and an on-site assessment.

ANAB and other firms that become recognized under the program will have the authority to accredit third-party certification bodies, also known as third-party auditors. Accredited certification bodies, in turn, will conduct food safety audits and issue certifications of foreign food facilities and farms, as well as the foods they produce. Thus, ANAB must first accredit one or more third-party certification bodies before VQIP can truly start.

Third-party certification under the Accredited Third-Party Certification Program will be a prerequisite for participation in VQIP. FDA also has the authority under FSMA to require certification under this program as a condition of entry for imported foods in limited circumstances, when specific, risk-based criteria are met. 4/

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Companies that experience significant business impacts from import delays, such as importers of perishable and short-shelf-life foods, may want to consider participation in VQIP. Please contact us if you would like to discuss participation in the VQIP program.

3/ ANAB is an organization jointly owned by the American National Standards Institute (ANSI) and the American Society for Quality (ASQ) based in Milwaukee, Wisconsin

4/ In order to use its mandatory import certification authority, among other things there must be a finding by FDA supported by scientific, risk-based evidence, that "the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States." Federal Food, Drug, and Cosmetic Act § 801(q).