

**To: Clients and Friends**  
**From: Erik Lieberman**  
**Re: Role of Foreign Government Employees in FSMA**  
**Date: November 6, 2014**

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Foreign government employees can play a number of roles under the Food Safety Modernization Act (“FSMA”) to conduct audits or inspections that exporters of food to the U.S. can provide to their U.S. importers to allow the importers to satisfy Foreign Supplier Verification Program (“FSVP”) food safety on-site audit requirements. FDA issued a proposed FSVP Rule in July 2013, and a supplemental proposed FSVP Rule in September 2014 (collectively “FSVP Rule”).

### Overview of FSVP Rule

The FSVP Rule requires importers to verify that their foreign suppliers produce food in compliance with the processes and procedures that provide at least the same level of public health protection as:

1. The Preventive Controls Rule for Human Food
2. The Preventive Controls Rule for Animal Food
3. The Produce Safety Rule

Importers are also required to verify that their foreign suppliers are producing food in compliance with:

1. Section 402 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (adulteration of food)
2. Section 403(w) of the FD&C Act (misbranding of food related to allergen labeling requirements)

The FSVP Rule requires that importers must conduct or obtain documentation of an onsite audit for hazards controlled by foreign supplier where there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals before initially importing food and annually thereafter unless the importer determines and documents that other activities such as sampling and testing, review of food safety records and less frequent auditing are sufficient.

Foreign government employees can play the following roles in verifying compliance of exporters or exported products to the U.S:

### Accredited Auditors/Certification Bodies

Pursuant to the Proposed Rule on Accreditation of Third-Party Auditors, a foreign government or agency of a foreign government may seek accreditation as an auditor or certification body (“CB”) from an FDA-

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recognized accreditation body, or in certain circumstances, directly from FDA<sup>1</sup>. Employees of the agency/government can act as audit agents and conduct audits so long as they are qualified.<sup>2</sup>

How can audits performed by accredited auditors be utilized by foreign exporters?

#### *Food Certifications*

Accredited auditors have authority to issue food certifications. FSMA gave FDA authority to require that certain imported foods be accompanied by a certification (or other assurance) that the food complies with the FD&C Act in order to be admitted into the U.S. (“MIC”-mandatory import certification). FDA can require a certification based on:

1. The known food safety risks of the food
2. The known food safety risks associated with the country, territory or region of origin of the food
3. A finding 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 U.S. in accordance with the requirements of the FD&C Act.<sup>3</sup>

**Note that food certifications may also be issued by unaccredited foreign governments:**

“An agency or a representative of the government of the country from which the article of food at issue originated (may issue a certification)...”<sup>4</sup>

#### *Facility Certifications*

Accredited auditors can issue facility certifications. FDA has informed the author that farms will also be eligible to receive these facility certifications. Food exports from manufacturing/processing plants and farms that receive such certifications will be eligible for expedited review and importation at the U.S. border pursuant to the Voluntary Qualified Importer Program (VQIP) that FDA is required to establish under FSMA. FSMA **does not** grant unaccredited foreign governments authority to issue facility certifications.

#### *FSVP Food Safety Verification*

U.S. importers may rely on audits performed by accredited auditors for purposes of complying with the onsite audit requirements of the FSVP regulation.<sup>5</sup>

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<sup>1</sup> Proposed 21 CFR § 1.640

<sup>2</sup> Proposed 21 CFR § 1.600

<sup>3</sup> 21 U.S.C. 381(q)

<sup>4</sup> Id.

<sup>5</sup> Proposed 21 CFR § 1.698

### What is the scope of an accredited audit?

Accredited audits “must be sufficiently rigorous to allow the accredited auditor/certification body to determine whether the entity is in compliance with the FD&C Act at the time of the audit. . .”<sup>6</sup> The audit is conducted for verifying compliance with the FD&C Act as applicable, rather than just specific regulations within it. Accredited audits appear to be significantly broader in scope than unaccredited audits. FDA has not specifically addressed the difference in scope of these two audits as of the date of this memo.

### Unaccredited Auditors

#### *Qualified Auditors*

A foreign government employee of an agency or government not accredited under FDA’s accreditation program can perform audits which may be used by U.S. importers to satisfy the onsite audit requirements of the FSVP Rule. To be considered a “qualified auditor,” the foreign government employee must be a “qualified individual” meaning that they “have the necessary education, training, and experience.” The foreign government employee is required to “have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum as recognized by FDA or be otherwise qualified through job experience to develop and implement a food safety system.”<sup>7</sup>

### What is the scope of an unaccredited audit?

Audits performed by qualified auditors for purposes of meeting the onsite audit requirement of the FSVP Rule must consider all FDA food safety regulations applicable to the food.<sup>8</sup> This scope is narrower than audits conducted by accredited auditors which much determine compliance with the FD&C Act. The FD&C Act includes FSMA and other food safety requirements (which are mostly implemented through regulations), but also includes requirements that go beyond food safety, such as nutrition labeling. FDA has not specifically addressed the difference in scope of accredited and unaccredited audits as of the date of this memo.

### Inspectors from Countries with Food Safety Systems Recognized by FDA

U.S. importers entering food from countries with food safety systems that have been officially recognized as comparable or determined to be equivalent to that of the U.S. do not have to conduct onsite audits or other forms of food safety verification for such food. The U.S. importer must however:

1. Document that the foreign supplier is in, and under the regulatory oversight of the FDA-recognized/equivalent country and the food imported is within the scope of the FDA-recognition/equivalency determination

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<sup>6</sup> Proposed 21 CFR § 1.651

<sup>7</sup> Proposed 21 CFR § 1.500

<sup>8</sup> Proposed 21 CFR § 1.506

2. Determine and document that the foreign supplier is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. The importer must continue to monitor the compliance status of the foreign supplier and take corrective action if information indicates that food safety hazards associated with the food are not being adequately controlled.

Inspections from inspectors in FDA recognized/equivalent countries that place a facility or farm in good standing under the country's regulatory authority thus exempt the U.S. importer from having to conduct food safety verification of the food under the FSVP rule. As of the date of this memo, New Zealand is the only country that is recognized by FDA.

### FSMA Authority Chart\*

Foreign Government Employee of:	FSVP On-site Audit	Food Certifications (MIC)	Facility Certifications (VQIP)	FSVP Exemption For Facility/Farm
Accredited Foreign Government/Agency	Yes	Yes	Yes	No
Unaccredited Foreign Government/Agency	Yes	Yes	No	No
FDA recognized/equivalent Food Safety System of Foreign Government	N/A	N/A	No	Yes

\*The above table looks at each authority discretely. For example, it assumes that the FDA recognized /equivalent food safety system of a foreign government is not also accredited. An employee of a government in a country with an FDA recognized/equivalent system could have authority to issue facility certifications if the country applied for and obtained accreditation.

Please contact Erik Lieberman at [erl@liebermanpllc.com](mailto:erl@liebermanpllc.com) or 202.830.0300 if you have any questions.