I. Introduction

On September 29, 2014, the U.S. Food and Drug Administration (FDA) published a supplemental proposed rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP), to implement the Food Safety Modernization Act’s (FSMA) requirement that food imported into the United States is produced with at least the same level of public health protection as is required for food grown and processed in the United States. The FDA issued this supplemental proposal as a result of feedback received from stakeholders meetings and comments submitted to the agency on certain key FSVP rule provisions during the initial comment period when the proposed FSVP rule was first published.

The FSMA FSVP rule supplemental proposal does not address all comments and concerns that were submitted to the FDA in response to the original proposals, but instead only addresses a limited number of significant rule provisions for which FDA’s current thinking has changed significantly or where additional comments are requested by the FDA. Importantly, all proposed FSVP rule provisions are still subject to change in the final rule, even those that have not been specified in the supplemental proposals.

PMA is pleased that FDA has provided a second opportunity for stakeholders to provide input and comments regarding specific proposed provisions of this important FSMA rule in order to assure that these regulations, when finalized and implemented, will best serve public health and food safety needs. FDA requests comments on the proposed approach and provisions by December 15, 2014.

As per this FDA proposed rule, food importers would now be required to develop foreign supplier verification programs to verify that food products being imported into the United States are grown, harvested, packed, manufactured and held under conditions and practices that are compliant with FDA’s FSMA produce safety rule and preventive controls rule for human foods.

An “importer of food” as per the FSVP proposal is the United States owner or consignee of the food at the time of entry, or, if there is no United States owner or consignee at the
time of entry, the U.S. agent or representative of the foreign owner or consignee. A “foreign supplier” of food as per the FSVP proposal is an establishment that manufactures/processes, raises the animal, or harvests food that is exported to the United States without further manufacturing/processing by another establishment.

A foreign supplier verification program, as per the FDA proposal, consists of the following seven components:

1. Compliance Status Review
2. Hazard Analysis
3. Verification Activities
4. Corrective Actions
5. Periodic Reassessment of the Foreign Supplier Verification Program
6. Importer Identification: (Dun & Bradstreet Identification Number)
7. Recordkeeping

Importantly, the FSVP supplemental proposal now requires that importers take appropriate verification measures based on the food and supplier risks, and the FDA has proposed a two-tier scheme for verification based on risk. The FSVP supplemental proposed rule amends the following key provisions:

A. Hazard Analysis
B. Supplier Verification
C. FSMA Rules Consistency (FSVP & Preventive Controls for Human Food)
D. Compliance Dates

II. Specifics of Supplemental Proposal Provisions

A. Hazard Analysis

The FDA is proposing that importers perform a comprehensive evaluation of food and supplier risks, in that an importer would be required for each food being imported, to analyze the hazards and conduct compliance status review of each foreign supplier. The intent of the compliance review is for the importer to assess whether the food or supplier has in the past been found in violation of FDA regulations. The FDA has included this compliance status review in response to comments received by the agency, in that too much emphasis in the original FSVP proposed rule was placed on importer hazard analysis, while not sufficiently requiring importers to consider supplier specific risks.

This broader hazard analysis and evaluation of risks would require importers to consider:

- the nature of hazards in a food,
- the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier’s ingredient supplier,
- the foreign supplier’s procedures, processes and practices related to food safety,
• applicable U.S. food safety regulations and information regarding the foreign supplier’s compliance with those regulations, and
• the foreign supplier’s food-safety performance history.

FDA is also requesting comment on whether or not importers should be required to consider hazards that may be intentionally introduced for purposes of economic gain as part of its hazard analysis.

B. Supplier Verification

The FSVP supplemental proposed rule now requires that importers take appropriate verification measures based on the food and supplier risks via a two-tiered, risk-based approach. The approach that the FDA is proposing would provide importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods. For food products where the foreign supplier controls the hazard in a food, there are two proposed risk classifications, which will determine what supplier verification activities will be required of the importer. These two proposed risk classifications and requisite supplier verification activities are as follows:

1) **SAHCODHA Hazards** – when there is a reasonable probability that exposure to the identified hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA). NOTE: This is comparable to the FDA criteria of a Class I recall.

Supplier verification activities would include:
• Annual on-site auditing of foreign suppliers or
• Importers would be allowed to use a different approach (possibly including less frequent auditing) only if they can establish that it will provide adequate assurance that the hazard is controlled.

2) **Non-SAHCODHA Hazards** – when there is a reasonable probability that exposure to an identified hazard will not result in serious adverse health consequences or death to humans or animals (SAHCODHA), but is still a hazard nonetheless.

Supplier verification activities would include:
The importer must determine what verification activity or activities from among several specified methods, which include but are not limited to:
• on-site auditing,
• sampling and testing,
• review of supplier food safety records, and
• any other appropriate method.
C. FSMA Rules Consistency (FSVP & Preventive Controls for Human Food)

To make the proposed FSVP rule consistent with the revisions to the proposed rules on preventive controls for human and animal foods, FDA has proposed the following revisions:

- changing the definitions of “very small importer” and “very small foreign supplier” to having no more than $1 million in annual food sales rather than the previously proposed limit of $500,000 in annual food sales, and
- deeming that importers that operate food facilities in compliance with any potential supplier verification provisions that may be included in the preventive controls rules are in compliance with any parallel FSVP requirements to avoid duplicative regulations.

D. FSVP Compliance Dates

Most firms would be required to be in compliance 18 months after publication of the final FSVP regulations; however, there are exceptions. For the importation of food that is also subject to the preventive controls rule or produce safety rule, the importer would be required to comply with FSVP regulations six months after the foreign supplier is required to comply with preventive controls or produce safety regulations. Note that the compliance dates for the preventive controls or produce safety regulations vary, depending on the rule and size of the operation.

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