THE VOICE OF FOOD RETAIL
Feeding Families Enriching Lives

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals Supplemental Proposed Rule[1]

Docket No. FDA–2011–N–0143

Dear Sir or Madam:

On September 29, 2014, the Food and Drug Administration (FDA or the Agency) published in the Federal Register a supplemental proposed rule entitled Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the "Supplemental Rule"). The Supplemental Rule revises the proposed requirements concerning compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities among other things. The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

FMI supported the enactment of the Food Safety Modernization Act (FSMA). We believe the regulations issued to implement section 301 of FSMA, if crafted in a manner consistent with the following comments will enhance public health and strengthen our nation's food safety regulatory system.

[1] 79 Fed. Reg. 58574 (September 29, 2014).

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Compliance Status Review

The previous Foreign Supplier Verification Program Proposed Rule ("Proposed Rule") included two requirements concerning importers' review of information related to the risk associated with foods and/or foreign suppliers:

1. A requirement to review the compliance status of each food to be imported and each foreign supplier being considered; and
2. A requirement to analyze the hazards in each food.

The Supplemental Rule consolidates these requirements into the risk evaluation requirements. In addition to requiring importers to consider the hazards they deem to be significant, importers are required to consider:

- The entity that will be applying the controls for the identified hazards, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier
- The foreign supplier's procedures, processes, and practices related to the safety of the food
- Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter or import alert
- The foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food and the supplier's record of correcting problems
- Any other factors as appropriate and necessary, such as storage and transportation practices

FMI supports this more comprehensive analysis. We believe it is more logical to consolidate requirements within a single risk evaluation than mandate such factors be considered separately.

Known or Reasonably Foreseeable Hazards; Use of the Term Significant Hazard

The hazard analysis in the Proposed Rule required evaluation of hazards that are "reasonably likely to occur." In the Supplemental Rule, FDA acknowledged that it might be confusing to use the phrase "hazards reasonably likely to occur" in both the Agency's HACCP regulations and the FSVP regulations (and preventive controls regulations), because the phrase has been used as the basis for determining hazards that need to be addressed in a HACCP plan at critical control points. In the Supplemental Rule, FDA requires importers to consider hazards that are known or reasonably foreseeable in their risk analysis rather than hazards that are reasonably likely to occur. FMI supports the use of the phrase known or reasonably foreseeable hazards. FMI

believes this will avoid the problem of confusing FSVP requirements with HACCP requirements.

In the Supplemental Rule, FDA has defined a known or reasonably foreseeable hazard as a potential biological, chemical (including radiological), or physical hazard that is known to, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

The Supplemental Rule requires importers to analyze the known or reasonably foreseeable hazards in a food, based on experience, illness data, scientific reports, and other information, to determine whether they are "significant hazards." A "significant hazard" is defined as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections, corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

FMI supports the use of the term "significant hazard."

Revisions Regarding Purpose of Supplier Verification

The Proposed Rule required the importer to conduct foreign supplier verification activities to provide adequate assurances that the hazards the importer had identified as reasonably likely to occur were adequately controlled. The Proposed Rule did not apply this provision to microbiological hazards in raw agricultural commodities that are fruits or vegetables and that would be subject to the produce safety regulations. Instead, the Proposed Rule stated that verification of these hazards should address whether foreign suppliers are producing these fruits and vegetables in accordance with the produce safety regulations.

In the Supplemental Rule, FDA requires that supplier verification activities provide adequate assurances that the foreign supplier is producing food in compliance with processes and procedures that provide at least the same level of public health protection as section 418 or 419 of the FD&C Act, if either is applicable, and is producing food in compliance with sections 402 and 403(w) of the FD&C Act.

FMI is concerned about a lack of guidance as to what constitutes "the same level of public health protection." FMI seeks more clarity from the Agency as to what constitutes "the same level of public health protection," and factors that importers should consider in making that determination.

Radiological Hazards

In the Proposed Rule, radiological hazards were included among the types of hazards (biological, chemical and physical) that importers must consider in their hazard analyses. Radiological hazards were in a separate category from chemical hazards in the Proposed Rule. In the Supplemental Rule, radiological hazards are a subcategory of chemical hazards. Treating radiological hazards as a separate category, rather than a subcategory, would be inconsistent with Codex and global HACCP standards. FMI supports FDA in taking the position that radiological hazards are a subcategory of chemical hazards.

Avoidance of Duplicative Requirements

In the Supplemental Rule, FDA specifies that if an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations, and the importer is in compliance with those requirements, the importer would be deemed to be in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the U.S). The Supplemental Rule similarly provides that if an importer's customer is required to establish and implement a risk-based supplier program under the preventive controls regulations and the importer annually obtains written assurance that its customer is in compliance with those requirements, the importer would be deemed to be in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the U.S. and the requirement to maintain records of the written assurances).

FDA has not however stated that if a facility sources food from an importer who has verified the safety of the food in compliance with FSVP requirements that such facility does not have to conduct its own redundant verification of the foreign supplier. The same logic that the Agency has applied in deeming an importer to be in compliance with the FSVP rule if its customer is in compliance with the supplier verification requirements of the preventive controls rules should similarly apply in the reverse situation. Namely, if an importer is required to comply with the FSVP requirements, and in compliance with such requirements in regards to a food, the customer of such importer should not be required to conduct its own verification of the same foreign supplier their importer has verified. Instead, the customer of the importer should be deemed to be in compliance with the supplier verification requirements of the preventive controls rules if they obtain a written assurance annually from the importer that the importer is in compliance with FSVP requirements for the food.

FDA has gone to lengths to make consistent the supplier verification requirements across the FSVP and preventive controls rules, and as such we believe requiring the customer of an importer who has already conducted a compliance verification on the foreign supplier in regards to a food, should not have to conduct their own separate verification. Requiring redundant verifications by customers of importers would impose unnecessary burdens and be inconsistent with the risk-based approach FDA is has taken in implementing FSMA.

Verification of Hazards Controlled by Foreign Supplier

In the Proposed Rule, FDA set forth two options regarding the requirements for foreign supplier verification activities. Under Option 1, for the importation of food with hazards controlled by foreign suppliers that are reasonably likely to cause serious adverse health consequences or death to humans or animals (SAHCODHA), the importer would be required, at a minimum, to conduct or obtain the results of an annual onsite audit to ensure that the foreign supplier is adequately addressing the hazards. In other situations involving less serious hazards, importers would have more flexibility to choose an appropriate supplier verification method.

Under Option 2 of the Proposed Rule, importers would have to select a verification activity from among onsite auditing, sampling and testing, review of the supplier's food safety records, or some other appropriate procedure, taking into account the risk presented by the hazard in the food, the probability that the exposure to the hazard will result in serious harm, and the food and supplier's status of compliance with U.S. food safety requirements.

In the Supplemental Rule FDA set forth a single "hybrid approach." The hybrid approach requires that when a SAHCODHA hazard in a food will be controlled by the foreign supplier, the importer must conduct (or obtain documentation of) initial and subsequent annual onsite auditing of the foreign supplier unless the importer determines and documents that other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances regarding the safety of the food and foreign supplier based on the risk evaluation conducted by the importer. Sampling and testing of the food, review of the foreign supplier's relevant food safety records, and other appropriate activities remain options for the "other" verification activities.

While FMI supported Option 1 in the Proposed Rule, we believe that the approach taken in the Supplemental Rule strikes an appropriate balance. The approach in the Supplemental Rule presumes that an annual onsite audit is required for SAHCODHA hazards controlled by a foreign supplier unless an importer can determine and document that other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances regarding the safety of the food and the risk of the foreign supplier. **FMI strongly supports annual onsite audits.**

Consistency with International Standards

The Supplemental Rule did not contain any discussion of the role existing global food safety standards can play in FSVP compliance. FMI believes that FDA should, to the greatest extent possible consistent with the requirements of FSMA, craft the Final Rule in such a manner as to provide for audits conducted pursuant to existing global food safety standards to satisfy the requirements of foreign supplier verification. FMI owns the Safe Quality Food Institute (SQF)—a GFSI-benchmarked scheme. GFSI schemes like SQF have proven to be very useful

verification tools and have improved food safety practices around the world. Our program is built on such standards and it would be enormously disruptive to have to change it. Mandating that farms and food facilities receive an additional redundant audit would impose unnecessary costs and compliance burdens.

Audit Reports

The Original Proposed Rules would have given FDA access to the underlying audit reports created through supplier verification activities. We believe this requirement would have limited an importer's ability to conduct a meaningful and thorough audit. In the Supplemental rule, FDA states that the audit report itself would not be accessible to the Agency; instead, the importer would be required to provide the conclusions of the audit and corrective actions taken in response to significant deficiencies. FMI agrees that maintaining the confidentiality of the underlying audit report will help to ensure a robust and thorough audit. However, we seek clarification on the term significant deficiency, including if this is includes additional hazards from SAHCODHA hazards.

Guidance on Annual Onsite Auditing

In the Supplemental Rule, FDA states that to address concerns that the revised proposal may allow too much discretion, and to assist importers in meeting the verification requirements, the Agency anticipates that it will provide guidance to industry on the circumstances (incorporating both food and supplier risks) under which onsite auditing of foreign suppliers and/or other supplier verification approaches are appropriate for providing adequate assurances regarding the safety of the food produced by the foreign supplier. FMI supports FDA's efforts to issue such guidance.

Definition of the Term Importer

The Supplemental Rule did not contain any discussion of the term importer as defined in the Proposed Rule. As noted in our comments on the Proposed Rule, FMI seeks greater clarification on the term importer under the rule.[2] In the supermarket industry, retailers and wholesalers may act as importers themselves, or may purchase product after it has already been entered into the U.S. The definition differs from the definition of ―"importer of record" contained within the Tariff Act.

Pursuant to the Tariff Act, an importer of record has the right to make entry. Importer of record is defined as the owner or purchaser of merchandise, or consignee, or a licensed customs broker when designated by the owner or purchaser or consignee. FMI seeks greater clarification as to the differences between the two definitions. A term―FSVP importer may be helpful for the Agency to use in guidance documents or the regulation itself to make the distinction clear.

Verifying the Supplier Verification Practices of Suppliers

As the Supplemental Preventive Controls Rules for Human and Animal Food both require facilities to conduct supplier verification, it remains unclear how importers will verify that their suppliers are verifying the food safety practices of their suppliers. FMI believes that FDA should provide further guidance on this matter in the final FSVP rule.

We appreciate your consideration of these comments. Please do not hesitate to contact me at sbarnes@fmi.org or (202) 220-0614 if you have any questions.

Sincerely,

Stephanie Barnes

Stephanie K. Barnes
Regulatory Counsel

[2] FMI Comments to FDA on FSMA Foreign Supplier Verification Program Proposed Rule, January 27, 2014.