THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

July 26, 2016

Brian Pendleton
Office of Policy
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Mr. Pendleton:

The Food Marketing Institute (FMI) appreciated the opportunity to meet with you on April 11 to discuss the Food and Drug Administration's (FDA's) implementation of the Foreign Supplier Verification Program (FSVP) and, in particular, its impacts on retailers. Your informative presentation and the following discussion were very helpful for our members. The retail industry is committed to compliance with FSVP and is working hard to develop programs that comply with this brand new regulatory paradigm. As a follow up to our meeting, we want to highlight a few particular areas where our members are seeking additional guidance or action from FDA in order to support their implementation efforts.

1. **Determining Who is Responsible for FSVP**

The most significant area of FSVP implementation that is posing challenges for our members is determining when they are responsible for FSVP. Under the final rule, the "importer" of food typically is the "U.S. owner or consignee," which is defined as "the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food." This threshold issue is critical for compliance, but also is proving very difficult to assess.

Our members face several hurdles in parsing the "importer" and "U.S. owner or consignee" definitions. One obstacle is that there typically are multiple parties in the distribution chain who can meet the "U.S. owner or consignee" definition. When multiple parties can qualify as the "importer," we expect that they typically will enter into a contract that governs who bears FSVP responsibility. FDA should honor this contract and only hold the party designated by the agreement liable for FSVP. Doing otherwise, and requiring accountability from each potential "importer," would create a tremendous disincentive for retailers to rely on another entity to act as the "importer" given that the retailer could still be liable. Additionally, that approach would introduce considerable duplication into the system, as multiple "importers" could each be conducting verification for the same food in order to manage their potential liability.

Another challenge is that the concept of "ownership" is unclear. There is no single determinative factor that governs what constitutes ownership and contracts typically do not speak to when "ownership" passes. There are several factors to balance when assessing ownership, including payment, risk of loss, and insurance coverage. Additionally, the concept of "ownership" is further complicated by the fact that many of our members' contracts allow them to reject food upon receipt if certain standards are not met, even if payment has been made in advance. It is unclear whether the retailer truly owns the food if they're still able to send it back to the supplier.

Assessing whether a retailer has agreed in writing to purchase the food also poses challenges, as ultimately retailers always agree in some form to purchase the foods that they sell. Whether this agreement occurs prior to the time of import will vary from transaction to transaction. This is particularly difficult to assess for standing orders and spot buys, as some of our members do not enter into formal written agreements governing the purchase of food but have various types of systems in place that result in store shelves being restocked.

Fundamentally, all of these challenges relate to the significant need for guidance from FDA about how to identify the "importer" and, in particular, the "U.S. owner or consignee." We need FDA to provide practical examples that reflect actual industry practices. For example, we would appreciate guidance that addresses very specific but common scenarios, such as the following:

> A retailer uses a small produce distributor to supply it with much of its requirements for bell peppers. The retailer places a purchase order for several hundred cases of bell peppers, but due to the season, the retailer does not know where the peppers will come from (Florida, Mexico or Peru). To fulfill this purchase order and purchase orders from other retailers that it does business with, the distributor imports a full container of bell peppers from Mexico into the US. Who is responsible for FSVP?

We would be pleased to work with FDA to help the agency better understand the retail purchasing supply chain and develop guidance specifically for retailers on this very important issue. We also would be happy to provide the agency with a list of additional common importing scenarios to use for building guidance.

2. Potential For Fraud with Importer Declaration

We are concerned about the potential for a company to be listed as the "importer" at entry even though the company has not authorized the entity completing the entry forms to identify them as such. The regulation simply provides that the name, email and unique facility identifier for the importer must be provided electronically when filing entry with U.S. Customs and Border Protection. There is no "check" mechanism, however, whereby FDA will confirm that the "importer' who is identified has authorized this designation. This presents the potential for fraud, as a company could be listed as the importer even though they have no knowledge of the import and, therefore, have not completed foreign supplier verification for the food. Building on the example above regarding imported bell peppers, consider the following scenario:

> Because the bell pepper distributor does not want to deal with the FSVP requirements, it looks up the D-U-N-S number for the most sophisticated retailer to which the peppers will be sold and provides their name, email address and D-U-N-S number on the Customs

declaration, thereby making the retailer the FSVP Importer. The retailer has no knowledge of this and has not authorized the distributor to list them.

Unapproved designation of a retailer is a legitimate concern, particularly considering the numerous outstanding questions about the definitions "importer" and "U.S. owner or consignee," as discussed above.

FDA should adopt a check mechanism whereby approval is needed in order to list a company as the "importer" at the time of entry. The agency should mirror the approach that U.S. Customs and Border Protection (CBP) takes to prevent fraud at the time of entry. CBP requires that a Customs broker must have a valid Customs Power of Attorney on file prior to transacting any Customs business on behalf of the Importer of Record. 19 C.F.R. § 141.46. Taking a similar approach and requiring the person designating the FSVP importer to have a Power of Attorney from the "importer" would enable FDA to audit whether the parties filing the import paperwork actually were authorized to list a given company as the "importer" and provide a remedy in the event of fraud.

3. Reliance on Existing Audit Schemes

Many of our members have voluntarily implemented supplier auditing programs over the last several years, including requiring suppliers to comply with audit schemes under the Global Food Safety Initiative (GFSI). The major audit schemes (including the Safe Quality Food Institute (SQFI)—a division of FMI) are actively engaged in assessing their compatibility with FSMA and making corresponding revisions to their requirements, but this process takes time (as FDA acknowledged in the FSVP preamble).

We are concerned by the agency's statement that until the schemes are updated "if an importer chooses to use a GFSI, [good agricultural practice], or other similar audit, the importer might need to supplement that audit to meet the requirements of the regulation or otherwise determine that the audit meets the [requirements]." 80 Fed. Reg 74226, 74288 (Nov. 27, 2015). This approach undercuts the great strides made toward harmonizing audits and preventing duplication. In the early years of FSMA implementation while the schemes are being updated, we encourage FDA to exercise enforcement discretion by acknowledging that existing audits under the GFSI umbrella are adequate. This approach would be practical, risk-based, and efficient.

4. Need for Guidance

We understand that FDA is hard at work on guidance development for FSVP. We urge the agency to issue draft guidance as soon as possible, as some implementation efforts are at a standstill or significantly hindered without further direction from FDA. Moreover, industry needs time to absorb the guidance and then adapt implementation programs accordingly, so we would like to have at least 1 year between when guidance is issued and the compliance date for FSVP. Accordingly, we encourage FDA to exercise enforcement discretion for FSVP compliance or formally extend the compliance date so that at least 1 year lapses between the date the draft guidance is published and when compliance is required.

We also encourage FDA to develop a model FSVP so that industry has insight on the agency's expectations. The agency could provide this model in its own guidance or through the FSVP training begin developed by the Food Safety Preventive Controls Alliance. As with guidance, our members

are anxiously awaiting the FSVP training program as a way to gain additional insight into FDA's expectations. We encourage the agency to work with the Alliance to expedite development of this training program to the extent possible.

5. Applicability to Food Contact Materials

As you know, there is considerable confusion and concern about the applicability of FSVP for food-contact materials. In particular, because the FSVP applies for all "food" it ostensibly applies for all food-contact materials, including food packaging, food equipment (e.g., slicer for deli department), and general food-contact merchandise (e.g., pots and pans; single use cups, plates, and utensils). Food-contact materials do not present the same food safety risks as conventional food, yet under the regulation a hazard analysis is still required to determine whether there are any hazards requiring a control for which verification activities are needed. Our members already face a tremendous new challenge with developing FSVPs and we are concerned that including food-contact materials both significantly broadens the scope of FSVP for retailers and deflects resources from other imported foods that pose more significant issues for food safety. Accordingly, we believe it would be inappropriate to regulate imported food-contact materials in the same manner as conventional food given the unique nature of these products and the limited (if any) benefit to public health that would result from doing so.

We understand that FDA plans to address this issue through draft guidance. As discussed above, we look forward to the release of this guidance and the opportunity to comment on the agency's latest thinking on this issue. We believe that the agency should narrow the scope of food-contact materials that are subject to the FSVP and recognize that you do not need to make a hazard determination for every raw and finished material except when there's an exceptional risk (e.g., ceramic plates that could contain lead). We're looking forward to receiving clarity on this issue through the agency's forthcoming guidance so that we can find a sensible and reasonable path forward for imports of food-contact materials.

6. TAN Transparency

The Technical Assistance Network (TAN) has the potential to be a very helpful tool for both FDA and industry, but its current structure is not allowing the system to live up to its potential. The agency regularly receives the same questions from multiple parties because the public has no transparency into which questions have been asked and answered. The agency then has to answer the same question multiple times.

This problem could be averted if FDA publicly posted all of the questions and answers from the TAN. We encourage the agency to model the "AskFSIS" approach, whereby the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA's FSIS) posts questions and answers in a searchable database. This enables industry to get answers without submitting questions to the agency, as well as to see what questions other people are asking. There is some concern in industry that the closed TAN system is providing some companies with an "advantage" for compliance because they have received information from FDA that other companies do not have. Publically posting all of the TAN content would alleviate this concern.

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We appreciate your consideration of our perspective as the agency continues to implement the FSVP. We look forward to a continued constructive dialog. Please do not hesitate to contact me if you have any questions.

Sincerely,

Stephanie Barnes
Chief Regulatory Officer
Food Marketing Institute

cc: Sharon Lindan Mayl, Senior Advisor for Policy, FDA Office of Foods and Veterinary Medicine