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Leslie Kux
Acting Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Reference: Docket No. FDA-2011-N-0143
RIN: 0910-AG64

Dear Acting Assistant Commissioner Kux:

The National Customs Brokers and Forwarders Association of America (NCBFAA) welcomes this opportunity to submit comments on the Food and Drug Administration's proposed rule, Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (78 FR 45729, July 29, 2013).

As the association representing licensed customs brokers, NCBFAA provides an important and unique perspective. Our members serve as the interface between importers and the Food and Drug Administration (FDA), Customs and Border Protection (CBP) and other government agencies, facilitating the entry of goods and assisting importers to comply with the various government requirements.

An underlying principle of the Food Safety Modernization Act (FSMA) is that primary responsibility for the safety of imported food is placed on the party who has knowledge and control over the supply chain – the U.S. owner, the consignee who purchases the product, or a U.S. person who assumes that role as the agent of the foreign owner or consignee. NCBFAA is pleased that FDA captured the intent of the law with its proposed definition, in which the FSVP "importer" is defined as "the U.S. owner of the food if there is one or the consignee if there is not a U.S. owner at the time of entry....If the article has not been sold or consigned at the time of U.S. entry, the importer would be the U.S. agent or representative of the foreign owner or consignee at the time of entry."

In the discussion about the proposed definition, the FDA explained that the importer is "the person who caused a food to be imported……This person has a direct financial interest in the food and is most likely to have knowledge and control over the product's supply chain." The FDA specifically pointed out that the FSVP importer "might be, *but would not necessarily be*, the importer of record" (emphasis added), since the importer of record might well be an intermediary with little to no knowledge of the product. This is an important distinction and we are encouraged that the FDA showed such a clear understanding of the nuances of the supply chain. This will help to ensure that the FSVP importer is in a position to know first-hand details about the product and its supplier – a necessary prerequisite to verifying the safety of the supply chain.

While we support the agency's approach to the definition of "importer," NCBFAA brings to your attention to the following concerns relating to the implementation of the proposed rule:

1. **Designating the FSVP Importer**: The identity of the FSVP importer will not always be clear. Is there a U.S. owner or consignee at the time of entry? If so, who is it and what is his/her DUNS number? If not, who is the U.S. agent of the foreign importer or consignee and what is his/her DUNS number? These questions should not be left to speculation or guesswork. To avoid confusion and inaccurate designations, we suggest that there be an affirmative requirement for the Importer-of-Record to provide the name and DUNS number of the FSVP importer on its entry declaration. As noted, the Importer-of-Record may or may not also be the FSVP importer. Nevertheless, the Importer-of-Record *is* the party responsible for the entry and, therefore, should be the party specifically responsible for identifying the FSVP importer and providing that person's DUNS number.

2. **Who Is The U.S. Agent?** When there is no U.S. owner or consignee at the time of entry, the proposed rule requires the foreign owner or consignee to designate a U.S. agent or representative as the FSVP importer. Yet, it is unclear how this "agent" for purposes of the FSVP is to be determined.

It has been suggested that that the same U.S. agent designated in the food facility registration system for purposes of Prior Notice under the Bioterrorist Act (BTA) will be used in this context. We strongly believe that the "U.S. agent " listed on the food facility registration should not automatically be designated as the FSVP U.S. agent.

The food facility agent originated under the BTA and was intended for the very limited purpose of notification and communication between the FDA and the foreign food facility. Following passage of FSMA, the FDA added payment of re-inspection fees as an additional responsibility of the food facility agent. Now, verification of the food supply chain may be added to the food facility agent's responsibilities. FDA must recognize the impact of this stacking liability. Many of the 300,000+ U.S. agents identified in foreign food facilities' registrations agreed to a much more limited role and will not be in a position to accept this drastically expanded scope of responsibility. In light of this, the FDA will need to allow ample time and opportunity for agents and foreign food facilities to reestablish financial arrangements.

3. **Flaws in the Current Food Facility Registration System**: If the U.S. agent for purposes of the FSVP is to be the agent listed in the food facility registration, FDA must address the flaws in the registration system *before* the proposed rule is implemented. Currently, a foreign food facility registers with the FDA and provides a name and contact information for its U.S. agent. There is no requirement that the named U.S. agent formally agree to serve as the agent or to confirm that he is the agent. In fact, a named U.S. agent may not even know he has been designated as an agent. While the FDA does send an email to the named U.S. agent in an effort to confirm his role, no response to the email is deemed to be acceptance. Yet, the system has no way of knowing if the email (provided by the foreign facility) for the designated U.S. agent is a valid, correct email belonging to the named agent. When the purpose of the U.S. agent was limited to notification/communication, this was not such a significant issue. Now, however, with a U.S. agent responsible for verifying the safety of the food product's supply chain, a more rigorous, transparent process is needed, whereby the U.S. agent knowingly and explicitly accepts this role.

4. **Unique Challenges Ahead**: As the FDA is aware, international trade today involves complex networks of supply chains. The supply chains of some products are particularly intricate and opaque, presenting a special challenge for both importers and the FDA. A good example is: green coffee. Overseas trading companies

typically bulk together small batches of green coffee beans from numerous growers. There typically is no U.S. buyer when the product arrives in the U.S. as the green coffee beans are eventually sold on the commodity exchange market to multiple roasters in the U.S. The product is warehoused by the foreign trading company or other intermediary until a sale occurs. One shipment of green coffee will typically originate from half a dozen growers and go through perhaps five intermediaries in the supply chain before entering U.S. commerce. Who will be responsible for verifying the safety of this supply chain? The U.S. agent listed on the FDA registration? Some other designated agent? Moreover, are any of these supply chain participants in a position to verify the safety of the multi-branched supply chain of a bulk commodity product like green coffee? We bring this to the FDA's attention to underscore the enormity of the challenges ahead and to urge the agency to adopt a flexible approach that reflects the true complexity of the various global supply chains.

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Again, NCBFAA appreciates the FDA's continued efforts to address the challenges of implementing FSMA and to seek input from stakeholders on the best way forward.

Sincerely,

Darrell Sekin
President