NATIONAL CUSTOMS BROKERS & FORWARDERS ASSOCIATION OF AMERICA, INC.

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Michael Taylor
Deputy Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane
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Dear Deputy Commissioner Taylor:

The National Customs Brokers and Forwarders Association of America appreciates this opportunity to comment on the Food and Drug Administration's (FDA) implementation of the Food Safety Modernization Act.

NCBFAA represents licensed customs brokers throughout the United States. Our members serve as the interface between importers and Customs and Border Protection (CBP), the Food and Drug Administration (FDA) and other government agencies, facilitating the entry of goods and assisting importers to comply with the various government requirements.

When a food product enters the U.S., who is the importer? That seemingly simple question lies at the heart of the import provisions of the Food Safety Modernization Act. After all, the import provisions of this new statute revolve around the "importer." The importer will be required to verify that each foreign supplier has processes and controls in place to assure the safety of his food products. The statute says the importer may even be required by FDA to make annual on-site inspections of the supplier's facilities or conduct lot-by-lot certifications as part of this verification.

Clearly, the importer must be the party that is actually responsible for the food product -- with first-hand knowledge about and control over the product and/or the producers in the supply chain.

The Food Safety Modernization Act defines "importer" as follows:

> "For purposes of this section, the term `importer' means, with respect to an article of food—
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> "(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or
>
> "(B) in the case when there is no United States owner or consignee as described in subparagraph

(A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States."

The definition requires further guidance. Which consignee is an "importer" in this context? Who is an agent or representative? How does a person become an agent? As the FDA works to clarify these issues, NCBFAA requests the agency to consider the following:

1. **Choose Substance over Form**: In general, the "importer" should be a person with a financial interest in the product. FDA should not rely exclusively on terms, such as consignee, agent, or importer-of-record, which are used in different ways in different contexts. For example, a consignee may well be the appropriate responsible party with a financial interest, but not necessarily. A consignee may also be a bank or a cold storage warehouse. Likewise, the consignee listed on the bill-of-lading for a product may not be the same person listed as the consignee on the commercial invoice. And, the "Ultimate Consignee" identified on an FDA Prior Notice filing may not be the "Ultimate Consignee" shown on the Customs entry document for the same product (since FDA defines the term as the first location where the product lands and CBP defines it as the invoiced party or final destination based on the terms of sale.) Therefore, the FDA must be cautious using commercial terms as shorthand for "Importer" under the FSMA.

2. **No Agency By Default**: When there is no U.S. owner or consignee to serve as the importer, the statute says "the U.S. agent or representative of a foreign owner or consignee" at the time of entry shall be the "importer." The term agent or representative in this context should not be loosely construed. Before a person is determined to be an "agent or representative" for purposes of food importations, FDA should require by regulation that an affirmative statement of representation signed by both parties be filed with FDA or a similar transparent process whereby the agent explicitly accepts this specific role for the purpose of FDA food importations. The responsibilities of being a U.S. agent for a foreign food supplier are significant and no one should have that responsibility forced on them by virtue of their presence in the supply chain.

3. **Recognize the Commercial Role of the Parties**: A customs broker is not an importer. Confusing the two is like confusing the travel agent with the traveler. A customs broker formalizes and transmits the declarations made by his client, the actual importer (who is generally either the U.S. owner of the goods or the ultimate consignee). A customs broker does not have a financial interest in the commercial shipment other than the fee he receives for processing the entry. Customs brokers do not take physical or legal possession of the product and they do not distribute the product in U.S. commerce. Customs brokers simply do not have the same level of visibility into the commercial transaction as the importer of the product, nor do they have the legal ability to gain such visibility. And, as a practical matter, customs brokers do not have the leverage to influence the actions or behavior of the foreign supplier.

4. **Do Not Mix Apples and Oranges**: In defining the term "importer", "consignee" or "agent" for determining the admissibility of food products, FDA must take care not to confuse definitions and terms used for other purposes under other statutes, such as the FDA's Prior Notice security filing, or by other agencies. For example, the Prior Notice filing requires a U.S. representative to be listed for the limited purpose of notification. This designation should in no way confer "agent" status for purposes of the Food Safety Modernization Act.

The Food Safety Modernization Act places primary responsibility for the safety of imported food on the people who have knowledge and control over the supply chain – the U.S. owner, the consignee who purchases the product, or a U.S. person who specifically takes on the role as the agent of the foreign owner for this purpose. This is as it should be. It will not serve the goals of the Act to place this responsibility on third-parties simply because they are at a convenient point in the supply chain, yet are not in a position to know first-hand details about the product or to control who supplies the product.

So we are back to the original question: who *is* the importer? We think the importer for FDA purposes should be the person who caused the goods to come to the U.S. – that is, the party in the U.S. with a financial interest in the product or a U.S. agent designated by a foreign manufacturer or supplier through a specific written agreement between the foreign entity and the U.S. agent and filed with the FDA. Either of these parties should be required to register with the FDA and receive a registration number, which would be provided at the time of entry. This would provide the certainty required for FDA and would ensure that a true party in interest is responsible for the food product.

NCBFAA welcomes the opportunity to work with the FDA as you develop the regulations to implement this important new law.

Sincerely,

Jeff Coppersmith
President

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