Submitted electronically via www.regulations.gov

December 15, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0143; Proposed Rule: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Dear Sir or Madam:

The National Coffee Association (NCA) applauds the work completed by the Food and Drug Administration (FDA) and is grateful for the opportunity to comment on the agency's supplemental proposed rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.

NCA represents the U.S. coffee industry, which generates $36 billion annually in retail and foodservice sales, and conducts over $5 billion in trade with 50 countries from Africa, Asia, and Latin America. In addition to the 2,300 roasters and importers, the industry is comprised of nearly 28,000 coffee cafés employing persons in every state and region. Through retail, restaurant, and coffee café sales, the industry serves approximately 175 million consumers annually. NCA membership includes roasters, coffee growers, importers and exporters domiciled within and beyond the borders of the United States.

Executive Summary

NCA greatly appreciates the significant changes FDA has made to the proposed rule, many of which are directly responsive to industry comments and would make the rules more risk-based and tailored to food safety. The approach proposed by the agency provides needed flexibility to determine the appropriate supplier verification activities based on the nature of the hazard, the entity that will be controlling the hazard, and the supplier's food safety system as a whole. NCA strongly endorses this overall approach. While we agree with many of the proposed changes, there are several revisions that would make the regulations more flexible to accommodate the variety of approaches to supplier verification that can all result in safer food. In the comments that follow, we outline the changes that would account for the diversity and complexity of the food supply chain and make the rules more workable.

Areas of Agreement with FDA's Proposed Changes

We agree with FDA's dual goals of implementing FSMA in a way that both protects the public health and is workable for the food industry. Both of these elements are vital to making the rules a success, and we appreciate the agency's consideration of our previous comments to further these goals. Specifically, the NCA supports the following elements of FDA's supplemental proposed rule on FSVP:

1. **Ability to Select Verification Activities Based on Supplier and Food Risk**: The NCA strongly supports FDA's selection of proposed "Option 2" for non-SAHCODHA hazards. We find that this approach provides importers flexibility in selecting the appropriate verification activity and frequency, based on an evaluation of the risk presented by the food and the supplier. It is crucial that importers of coffee have the ability to conduct verification activities commensurate with its low-risk profile.

2. **No Written List of Suppliers**: The NCA agrees with the agency that importers should not be required to maintain a list of suppliers. Instead, importers should be required to have in place procedures to ensure that food is only received from approved suppliers. This change is well-tailored to furthering food safety and consistent with current industry practices. We also agree that unapproved suppliers may be used on a temporary basis, when necessary and appropriate, to the extent the food has been subject to verification activities before use or distribution.

3. **No Stand-alone Requirement for a Compliance Status Review**: The NCA supports FDA's repositioning of the proposed requirement for a compliance status review. We agree with this change in position because, as the agency has recognized, this is a task that does not improve food safety nor is it consistent with industry practice. We address review of a supplier's compliance history in further detail below.

4. **Confidentiality of Audit Reports**: The NCA supports FDA's recognition that the confidentiality of the full audit report must be maintained to encourage open and honest audits of suppliers. Absent such confidentiality, suppliers may be reluctant to submit to the transparent type of audit needed for a successful supplier verification activity.

5. **Compliance with Domestic Supplier Verification Requirements**: The NCA endorses the approach proposed by the agency for importers that are also subject to the domestic supplier verification program, under which companies in compliance with the domestic supplier verification requirements are deemed to be in compliance with most FSVP requirements. This approach appropriately focuses on food safety and avoids duplication, and is particularly helpful for our members who source domestic ingredients or raw materials, such as Kona from Hawaii for coffee blends.

6. **Customer's Compliance with Domestic Supplier Verification Requirements**: FDA has proposed that if an importer's customer is subject to the domestic supplier verification requirements for the imported food, and provides a letter stating that it is compliant with those requirements, then the importer is deemed to be in compliance. The NCA strongly supports this provision, as in some cases the entity that is the importer may not be the party in the best position to conduct verification activities, but rather their customer is better suited to verify the food and supplier.

In the comments below, we provide relevant background on the importation of coffee and identify areas where we believe further revisions are needed to achieve more outcome-based and workable rules.

Background on Imported Coffee

There are several attributes unique to coffee that we ask the agency to bear in mind as it considers these comments:

1. **Green coffee beans, caffeinated or decaffeinated (hereinafter referred to as "coffee"), are nearly always imported.**

2. **Coffee is a low-risk commodity with regard to potential food contamination.** Coffee is a dry commodity in its green state and has minimal susceptibility to spoilage. As such, coffee is inherently a low-risk, raw agricultural commodity, which marginalizes any concerns about contamination due to inadequate safety controls in origin. Coffee is not associated with the types of microbial or food allergen concerns that would normally present a potential Class I recall-level risk. Intentional contamination is also amply addressed through coffee industry participation in the Customs-Trade Partnership Against Terrorism program (C-TPAT), the voluntary supply chain safety program conducted by the U.S. Customs & Border Protection (CBP) agency of the Department of Homeland Security (DHS).

3. **Coffee is virtually always roasted, and the foreign supplier is not typically relied upon to control hazards.** Coffee is consumed by roasting at high temperatures followed by brewing. High-temperature roasting effectively and significantly minimizes and prevents biological hazards.

4. **Coffee is a commingled raw agricultural commodity.** Coffee is typically sourced from foreign farms, which sell the beans to intermediaries, cooperatives, millers, or exporters. As such, the foreign source of coffee is the supplier of a commingled raw agricultural commodity.

We believe the supplemental proposed rule rightly accounts for these unique attributes of imported coffee, i.e., that it is a low-risk commingled raw agricultural commodity for which foreign supplier verification requirements should be accordingly limited. NCA supports the general approach taken by the agency, whereby the requirement to conduct supplier verification activities does not apply to the extent the importer controls the hazards or the importer's customer controls the hazards. For most imported coffee, all significant hazards are controlled in the U.S. by the importer or the importer's customer. Under proposed section 1.504(g), these importers would appropriately be subject to only limited FSVP requirements. We believe this approach fully meets both the letter and the spirit of FSMA and provides sufficient protection for consumers.

Areas for Further Revision to Make the Rules More Flexible

The NCA requests that FDA make a number of fine-tuning changes to ensure the rules are workable.

1. Flexibility in Factors to Consider in Selecting Verification Activities

As discussed above, the NCA applauds the agency for the flexible approach taken for selection of verification activities. The proposed regulations envision that importers are to consider a number of factors in making this determination, including the nature of the hazard; the party that is controlling the hazard; and the supplier's food safety system, compliance with FDA food safety regulations, and performance history. In general, this proposal is consistent with best practices of considering both the material risk and the supplier risk.

We are concerned, however, that the codified language is unnecessarily prescriptive and fails to account for the range of ways in which supplier verification may be conducted. In particular, while each of the five enumerated factors is often relevant to the supplier risk evaluation, not all factors are necessarily considered as part of the process of selecting the verification activity.

For example, to the extent an importer has not previously used a supplier, it would be unable to assess the supplier's performance history at the initial stage of choosing the appropriate verification activity.

For importers of coffee in particular, what matters most for supplier verification purposes is the inherent risk of the product (for which coffee is inherently low) and the risk of the supplier (largely determined by the importer's historical track record with that supplier). The availability of FDA Warning Letters or Import Alerts that pertain to foreign suppliers is sketchy at best. Given the unique nature of our industry, there is a very low likelihood that even an extensive search would result in any responsive information since FDA understandably does not place a high priority on inspecting exporters of low risk products. Therefore, consideration of the compliance of the foreign supplier with FDA food safety requirements should only be required where it is appropriate to the specific food and supplier. Accordingly, we request that FDA add the term "as appropriate" to proposed § 1.505(a)(1) in order to clarify that the factors listed need only be considered to the extent they are appropriate to the specific food and supplier.

Similarly, each factor may not be considered at the initial stage of choosing the verification activity, although these factors may be considered as part of the overall risk evaluation, decision to approve the supplier, or reassessment of the verification activity selected. Therefore, FDA should also consider revising the language to state that these factors are to be considered "In determining whether to approve a supplier," rather than "in determining appropriate verification activities" in light of the fact that these factors may not be considered at the stage of determining the appropriate supplier verification activity or tool, but instead may be considered as part of the decision to approve the supplier.

Taken together, we recommend the following changes to the proposed language:

> Proposed 1.505 What risk evaluation must I conduct?
>
> *Evaluation of food and supplier risks*. (1) In determining <u>whether to approve a supplier</u>, you must consider <u>the risks associated with the food and the supplier, including</u> the following <u>as appropriate</u>:

2. Documentation for Suppliers that are Farms and are Exempt from the Produce Safety Rule

The NCA agrees with FDA that where an importer receives food from a supplier that is an exempt farm under the produce safety requirements, the importer should be exempt from conducting supplier verification activities. However, this exemption would be contingent upon the importer obtaining a letter of assurance from each such farm that it is producing the food in compliance with the Federal Food, Drug, and Cosmetic Act.

The NCA has serious concerns with this documentation requirement, as coffee is a commingled raw agricultural commodity[1] and in many cases the identity of the farm supplying the coffee is simply not known. Coffee may be grown by hundreds of small farmers and then shipped to a mill, where the beans are commingled, processed, dried, and prepared for shipment, and then shipped to the importer. Some mills do not have the capability to trace coffee back to individual farms due to commingling. Only in the case of large farms (which are in the minority in the industry) or in the case of certain countries' in-origin trade practices, is it possible to trace

[1]/ As explained in our comments on the original proposed rule, it is our understanding that coffee is exempt from the produce safety requirements because it is subject to further commercial processing that is a kill step (i.e., roasting).

imported containers of coffee to a specific farm or set of farms. The mill or exporter in the producing country may have the ability in some circumstances to trace the coffee to farm, but the importer in the U.S. would not have that ability. Moreover, the proposed documentation requirement would exceed the statutory authority under FSMA for traceability. For raw agricultural commodities that are not fruits and vegetables, such as coffee, the statute limits traceability to one step back. If importers were required to trace the specific farm that harvested the coffee supplied to the mill, cooperative, or exporter, this would in most cases be a requirement to trace more than one step back. [2] Moreover, FDA has already made a determination that produce that is subject to further commercial processing that provides a reduction in microorganisms, such as coffee, presents minimal or no risk. Therefore, adopting a documentation requirement for coffee would not have any added value to food safety.

For these reasons, we strongly recommend that FDA delete the proposed requirement in § 1.505(d)(4)(ii) that the importer obtain letters of assurance from farms exempt from the produce safety rule.

More broadly, we reiterate our previously submitted comments regarding which entity is the foreign supplier of coffee. We asked FDA to affirm that, for imported coffee, the importer must only look "one step back" in the supply chain to assure that the coffee exporter is taking reasonable steps to ensure that the commingled raw agricultural commodity is not adulterated under U.S. law. Coffee importers should be given broad flexibility on how to best accomplish that goal. We also ask FDA to confirm our interpretation that where coffee is sent from farms to a mill, which then commingles and extracts the bean from the cherry by fermentation, washing, or drying; the mill, cooperative, or exporter is considered to be the "foreign supplier," rather than the farm. This stands to reason because these entities process the food in more than a de minimus way, and thus meet the proposed definition of "foreign supplier."

3. Documentation for Hazards Controlled by the Importer's Customer

FDA has appropriately proposed that where the importer or the importer's customer controls all significant hazards, the requirements to conduct a risk evaluation and conduct supplier verification activities do not apply. Where the importer's customer controls the hazard, the importer would be required to annually obtain a letter from the customer providing assurance that it has established and is following procedures that will significantly minimize or prevent the hazard. The NCA is concerned that this proposed documentation requirement is impractical and would not contribute to food safety. This is particularly true for low-risk commodities such as coffee, for which the hazards are well-controlled by the importer's customer if they have not already been controlled by the importer.

Coffee, as a raw agricultural commodity, moves through a succession of transactions from importer to manufacturer, and the importer may have no direct contact with each eventual customer. Requiring importers to obtain a letter from each customer would be a time- and resource-intensive paperwork exercise. In addition, a letter from the customer is not necessary for food safety because the customer has an independent legal responsibility to assess and control hazards within its facility. It is the responsibility of each party in the supply chain to understand the products and ingredients it receives, analyze the potential hazards in those materials, and manage them appropriately. This is the fundamental principle of FSMA. Moreover, coffee is a raw agricultural commodity subject to roasting before it is consumed. There is no need for coffee importers to obtain a letter providing assurances that

---

[2]/ Similarly, the records traceability requirements under the Bioterrorism Act of 2002 limit identification of the foreign supplier to the last party in possession of the coffee before it is shipped to the U.S. FDA should seek to obtain consistency with the rules issued under the Bioterrorism Act.

the hazards will be controlled. FDA should recognize that this approach would not improve the safety of food, and should delete the requirement to obtain annual customer letters.

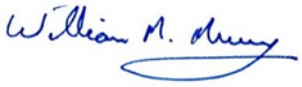
4. Exemption for Intra-Company Shipments

The NCA supports an exemption from the supplier verification requirements for intra-company shipments, i.e., where the importer receives food from an entity that is owned by the same corporate parent. In these instances, supplier verification is not necessary and would not contribute to food safety. The supplier is under the same corporate ownership, and therefore falls under the same corporate food safety program. Requiring the importer to verify related entities would be duplicative. We therefore support an exemption for intra-company shipments where the supplier and importer are both under the same corporate parent ownership.

* * *

We appreciate the opportunity to submit these comments and look forward to continuing to work with the agency to ensure that FSMA implementation is a success.

Respectfully submitted,



William M. Murray, CAE
President and CEO