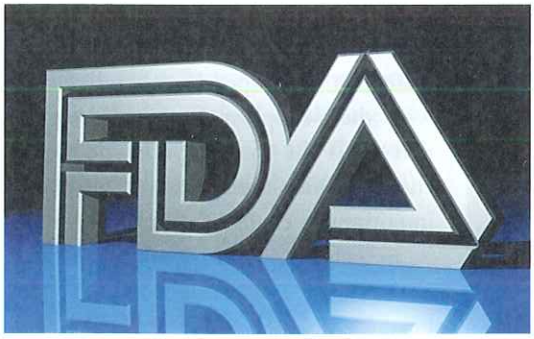
Impact of the FSMA on the Green Coffee Trade



Since the Food Safety Modernization Act (FSMA) was signed into law in 2011, the FDA has issued regulations covering seven components of the Act. If green coffee beans are not designated as an exempt food product under the proposed regulations still pending implementation, there will be numerous new responsibilities and costs associated with compliance. By Don Pisano

One of the great things about growing up in the United States was knowing that even if the rest of the world went to hell in a hand-basket, we were fairly self sufficient. We could produce our own food, fuel and everything one could need to survive, although we might have to do without some fruits, nuts and exotic foods we had grown to enjoy. Of course, we could never grow enough coffee in Hawaii and Puerto Rico to fill our daily desires. Today, approximately 15 percent of the US food supply is imported from all corners of the earth including everything from raw agricultural products to fully prepared foods, packaged and ready for human consumption.

While there always has been instances of food-borne illness, shipments of tainted food, baby formula, toothpaste and pet food imported from China caused a great deal of alarm among American consumers. This gave our representatives in Washington a cause that they could seize upon and demonstrate that they really had some value. Considering the significant lack of confidence and positive feelings about our elected officials, here was an opportunity that they could be seen as champions of the American consumer. Unfortunately, instead of focusing their efforts on the specific problem or region from where the problems originated, they decided they would treat all food products as suspect until proven otherwise—an extraordinary over-reach, as Congress is prone to do. Thus, the Food Safety Modernization Act (FSMA) was born. Once signed into law on January 4, 2011, the Act required the United States Food and Drug Administration (FDA) to develop the regulations to comply with the Act's intent on seven major components covering: Preventive Controls for Human Food, Produce Safety, Foreign Supplier Verification Programs (FSVPs), Accreditation of Third-Party Auditors, Preventive Controls for Animal Food, Intentional Adulteration and Sanitary Transportation of Food and Feed.

The FDA has since issued proposed regulations covering all seven areas. However, only the first two have actually been put into effect. Key parts within the first two regulations require the importer to identify any shipment previously refused by another country for entry, and allows for the FDA to perform inspections of domestic and foreign facilities. In the event that a follow-up inspection is required, significant hourly fees–USD $237/hour for domestic facilities and $302/hour foreign facilities–including travel time plus expenses will be assessed to cover the government personnel's costs involved. For foreign facilities, these fees will be assessed against the foreign food facility's designated US Agent. This is not something the US Agents signed on for when this role was created in 2002 to allow the FDA to have a domestic contact who it could communicate with in English. As a result, many of these agents have opted out of the program or began charging the facilities represented a significant annual fee to continue accommodating them in this role that now carries a financial burden.

The other five regulations pending final enactment put the onus on the importers or owners of the goods to ensure that their foreign suppliers have adequate food safety and preventive controls in place and follow "Good Manufacturing Practices" in order to ensure all imported foods are as safe as domestically produced food, with few exceptions, and that transport of those goods are conducted under safe and sanitary conditions. Although the regulations have been delayed beyond the original deadline, there is now an agreed timetable for the final rules to be issued:

- Preventive Controls for Human Food
  August 30, 2015
- Preventive Controls for Animal Food
  August 30, 2015
- Produce Safety
  October 31, 2015
- Foreign Supplier Verification Program
  October 31, 2015
- Accreditation of Third-Party Auditors
  October 31, 2015

- Sanitary Food Transportation
  March 31, 2016
- Intentional Adulteration
  May 31, 2016

Over the past three years, the National Coffee Association (NCA), New York, working through its Logistics Committee and Government Affairs Committee, has submitted comments on many aspects of the proposed regulations as they became available for comment. A key theme that has been repeated by the NCA is the suggestion that green coffee beans be designated as exempt from the produce safety regulation. Considering that green coffee is a raw agricultural commodity subject to inspection, cleaning and handling prior to roasting, or what is known as a "kill step," the request for exemption is clearly reasonable, having no real impact on food safety, and would prevent adding unnecessary operational and financial burdens on an industry providing livelihoods to millions of people in the lesser developed world. In the event that green coffee beans are not designated as an exempt food product under the proposed regulations still pending implementation, the combined regulations to be imposed on green coffee importers will be the most significant change to the coffee industry since the Bioterrorism Act of 2002.

The coffee importer will be required to ensure that their suppliers are maintaining safety standards similar to domestic food processors. To do that, the importer will have to gain in depth knowledge of their suppliers' controls for coffee processing, handling, housekeeping, safety, risk assessment and preventive controls, along with keeping records to be made available in English.

The FDA's Inability to Monitor Compliance

Clearly, the FDA is currently in no position to monitor compliance with these new regulations for anything more than a small fraction of foods imported into the United States. It is quite difficult to conceive that the FDA will ever be in a position to fully administer their proposed regulations as they become effective. But the FDA's lack of capacity to administer the regulations will not relieve the industry from compliance with the regulations when required.

A case in point, under the Preventive Controls for Human Food regulation already in effect, and as mentioned above, the role of the US Agent for a "Foreign Food Facility" has changed dramatically and burdened the agent with new and significant financial responsibilities. However, the FDA has not advanced their system and controls to effectively manage the US Agent appointment process. These issues have been addressed with the FDA yet no apparent actions have been taken to resolve this significant impediment to fulfilling their own clear food-safety objectives.

It remains to be seen whether or not the FDA will heed the call of the NCA and designate green coffee as an exempt product whereby relieving the import community of the very significant new responsibilities and costs associated with them. But in the event that green coffee is included in the non-exempt category, much work must be done industry wide. While it is understandable that individual companies may want to jump out in front of the regulations, this approach may lead to confusion and inconsistent standards among the producers. It would be far more beneficial for the industry to work collaboratively to draft a standard "best practices" guideline with minimum requirements and recommended protocols.

This process could leverage the security procedures required for C-TPAT credentials against any overlap with the Voluntary Qualified Importer Program. We may also be able to engage accredited third-party inspectors to perform inspections on behalf of the trade as a whole in order to minimize the costs for the individual importer.

All of us must continue to closely monitor the regulatory developments and enforcement dates. Any meaningful progress on food safety in the coffee business will require open and honest collaboration among the industry's leaders along with full engagement with the US Food & Drug Administration.

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