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December 15, 2014

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

Re: FDA-2011-N-0143 -- Revised "Foreign Supplier Verification Program (FSVP) for Importers of Food for Humans and Animals."

American Farm Bureau Federation (Farm Bureau) is the nation's largest general farm organization, representing approximately 6 million member families and growers of virtually every commodity. The implementation of the Food Safety and Modernization Act (FSMA) is a major challenge and we appreciate Food and Drug Administration (FDA) recognizing that farmer and rancher input is integral in ensuring food safety goals are met.

We commend the FDA for issuing this Supplemental Notice of Proposed Rulemaking and are pleased to present viewpoints from the farm level on the modifications to the initial foreign supplier verification rule. Moreover, we appreciate clear acknowledgment of concerns raised in Farm Bureau comments dated January 27, 2014, and the resultant modifications seen in the revised FSMA Proposed Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (FSVP) rule.

General Foreign Supplier Verification Program Comments

AFBF has a vital interest in how food safety is practiced, perceived and regulated. We believe that, while the U.S. food production system is among the best in the world, science-based, collaborative, improvement is always an important principle.

By their nature, food systems are biological and thus not failsafe nor ever "zero risk." Recent improvements in reducing foodborne illness have occurred despite new challenges for food safety; such as changes in the typical American diet that include more imported foods and more food consumed away from home. The U.S. now imports food from more than 150 different countries through more than 300 ports of entry. About half of fresh fruits eaten in America are grown outside of the country, and these imports allow consumers to enjoy their favorite produce year-round. Trade in food permits a more varied and customized diet suited to today's consumer preferences. It permits our farmers and other food producers to sell their goods abroad. But it also means that food safety requires enhanced attention to the global food supply, and FDA must apply and enforce any new produce safety standards on imports in a manner similar to that for domestic producers.

It is critical when promulgating FSVP requirements to ensure that the importers' foreign suppliers are producing in compliance with processes and procedures that provide at least the same level of public health protection as required of domestic suppliers. The rules on domestically produced items must be applied in the same manner as rules on imported items covered under the FSVP rules. If this is not

achieved, the FSMA rules could be considered as constituting a trade barrier that may then be open to a World Trade Organization (WTO) challenge.

We also point out the necessity for FDA to have adequate resources to implement this rule. FDA must have sufficient personnel and systems in place to inspect importers and ensure that those importers have and implement strong supplier verification programs. Without robust enforcement, the FSVP rules which extend those standards to imported produce are meaningless from a food safety perspective.

Exemptions and Exceptions

In the proposed supplemental rule, FDA extends the monetary value ceiling of $1 million established in the preventative controls for human food rule to "very small importers" and "very small suppliers." Additionally, FDA seeks comment on how and whether to take into account the changes in the exemptions under the Produce Safety and Preventative Controls for Animal Feed rules.

As noted in our initial comments, because the same standards and exemptions for domestic produce must also be extended to imported produce in order to comply with WTO rules, the proposed regulatory exception for growers with sales of $25,000 per year or less would be particularly relevant when applied to foreign suppliers – in fact, even more so with the new distinction of sales limited only to produce rather than all food. While we believe that few, if any, domestic growers would qualify for this exemption, its consequences for imports are dramatic. The amount of produce production required to reach the equivalent of $25,000 U.S. is vastly different in numerous foreign countries, many of which are significant produce exporters to the US. For example, while Chinese apple production is the world's largest, it is the product of many small farms that make less than $25,000 U.S. per year.[1] Under the small farm exception in the proposed rule, the vast majority of apples imported from China would be exempt from the proposed rule, putting U.S. producers at a significant competitive disadvantage, and creating a differential and confusing system of food safety regulation U.S. consumers.

We continue to have concerns about providing modified treatment of very small importers (as defined in § 1.500) and very small foreign suppliers (as defined in § 1.512). As proposed in the original § 1.512, modified FSVP requirements would only mandate written assurance of compliance rather than hazard-analysis and verification. FDA already estimates that 59 percent of processed food suppliers and 93 percent of raw produce suppliers would fall under this category, which would leave a large amount of imported foods outside the program.

Compliance with International Trade Protocols

FDA's supplier verification regulations must conform with international standards and agreements. Section 404 of FSMA states that the provisions of FSMA are not to be construed in a manner inconsistent with U.S. international obligations. As a WTO member, the United States is required to act consistently with its WTO obligations, including those contained in the Agreement on the Application of Sanitary and Phytosanitary Measures.

[1] Follow your labels: American apple juice is a product of China, Christian Science Monitor July 2013. http://www.csmonitor.com/World/Global-Issues/2013/0721/Follow-your-labels-American-apple-juice-is-a-productof-China

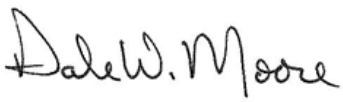
Farm Bureau generally agrees with FDA's position, as explained in the preamble of the proposed FSVP rule, that the agency is obligated to take a parallel approach to domestic supplier verification within its preventive controls regulations to enhance compliance with WTO obligations and ensure trade access. Importantly, the United States is the world's largest economy and the largest exporter and importer of goods and services. Trade is critical to our country's prosperity – U.S. food and agricultural exports reached an all-time high in 2013 at more than $152 billion, and supported an estimated one million jobs on and off the farm.

Therefore, FDA should take a cautious and balanced approach when implementing the requirements associated with foreign supplier verification, recognizing such requirements have potential trade implications and that obligations placed on foreign suppliers also will be imposed in a parallel manner on domestic suppliers. Such requirements must be flexible in application and commensurate with the both the risk associated with the food or feed product and the supplier itself so as to avoid unnecessary and burdensome costs.

Conclusion

We are committed to improving food and feed safety in a targeted, scientific, and risk-based manner. We look forward to continuing our working partnership with FDA to promote the safety of the food and feed provided and utilized by America's farmers and ranchers.

Sincerely,



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