



December 15, 2014

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
<http://www.regulations.gov>

Re: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals – Supplementary Proposal. Docket No. FDA-2011-N-0143; RIN 0910-AG64

The United Fresh Produce Association (“United Fresh”) appreciates the opportunity to comment on the supplementary proposal to the proposed regulation *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals* (“FSVP rule”).

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

Hazard Analysis

As noted in our January 2014 comments to the proposed rule, we believe that FDA has exceeded the Congressional mandate, to hold food imported for consumption in the U.S. to the same food safety standards as food produced domestically, in several of the proposed requirements. We interpret the Congressional intent to be that food, including produce, should be held to the same standards, whether sourced domestically or imported. To do otherwise puts one entity at an unfair, competitive disadvantage to the other and, if the disadvantaged entity is foreign, risks a World Trade Organization (WTO) challenge.

The proposed Produce Safety rule limits a farm’s hazard controls to microbiological hazards, FDA’s rationale being that foodborne outbreaks and illnesses linked to fresh produce sourced in the U.S. have all been due to the presence of microbiological pathogens, and that public health risks due to the presence of chemicals or physical hazards including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens, physical hazards, and radiological hazards, are not reasonably foreseeable. We submit that the same is true of fresh produce imported to the U.S.; i.e., FDA’s data reveal no outbreaks linked to chemical or physical hazards in imported produce, there have been no examples of economically motivated adulteration of

fresh produce, and government surveillance of imported produce has never detected chemical contamination on fresh produce at levels reasonably likely to cause illness. Indeed, FDA has stated (79 FR 58579) an intent that *“for a RAC that is a fruit or vegetable, an importer would not be required to conduct a hazard analysis regarding the microbiological hazards that might be reasonably likely to occur with this food. Instead, the importer would need to verify that this kind of food is produced in compliance with FDA’s produce safety standards, once finalized, or equivalent standards.”* Further, revised § 1.506(c) expressly states that *“Your foreign supplier verification activities must provide adequate assurances that the foreign supplier produces the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act.”*

However, § 1.504 continues to require importers to perform or evaluate a written hazard analysis equivalent to that required under the proposed Preventive Controls rule, even when importing fresh produce (excepting for microbiological hazards). While FDA may consider this a minor detail (the hazard analysis would simply declare that there are no foreseeable chemical or physical hazards or hazards that may be intentionally introduced for purposes of economic gain), it would remain a continual regulatory burden, for every supplier and every commodity imported, for which an importer could be deemed in violation of the regulation if not performed or recorded.

Therefore, instead of § 1.504(e) *“Microbiological hazards in raw agricultural commodities that are fruits or vegetables. If you are importing a raw agricultural commodity that is a fruit or vegetable, you are not required to determine whether there are any significant microbiological hazards in such food”*, we encourage FDA to simplify the requirement for importers of fresh produce, whether directly from a farm or from a post-harvest packing/holding operation, to something like *“Hazards in raw agricultural commodities that are fruits or vegetables. If you are importing a raw agricultural commodity that is a fruit or vegetable, you are not required to determine whether there are any significant hazards in such food”* and limit such importers’ responsibility to verification that their suppliers are in compliance with the requirements of the Produce Safety or, if importing from a registered facility, with the pertinent requirements of the Preventive Controls regulation.

Foreign Supplier’s Suppliers

In our January 2014 comments to the proposed rule, United Fresh reminded FDA that the fresh produce supply chain is more complex than is common for most ingredients in manufactured foods, and we were concerned that this was neglected in FDA’s specific proposal that importers of fresh produce must obtain documentation of an audit of that supplier, and that the supplier intended is the one responsible for controlling the identified hazard which, for fresh produce, would be the grower. While some imports will be direct from the grower, many will be through intermediates, such as packinghouses or aggregators that may purchase produce from many small growers, or through brokers that do not take physical possession of the produce. Indeed, there may be situations where there are several steps in the supply chain between the grower and the importer. With current industry practices, importers may not have information of the source of produce beyond the direct supplier. In our comments, and reiterated here, we reminded FDA that the Bioterrorism Act required operations only to be able to track product one step forward and trace product one step back. We contend that FDA’s intention that importers have knowledge and documentation of the supplier’s suppliers exceeds this statute. Further, such a requirement will require a massive change in the produce supply chain, where the

identity of a broker's or aggregator's suppliers is often proprietary information, and where substitutions of suppliers is a frequent necessity. We are concerned that compliance with FDA's intent will incur expenses not considered in FDA's economic impact, and will encourage entities that cannot comply to falsify documents. Therefore, we reiterate that an importer's regulatory responsibility under this rule should be limited to verification of their direct supplier's compliance with the relevant regulations.

Additional Specific Comments

§ 1.502(d) *Importers whose customer is subject to section 418 of the Federal Food, Drug, and Cosmetic Act. If your customer is required to establish and implement a risk-based supplier program under § 117.136 or § 507.43 of this chapter for a food you import, and you annually obtain from your customer written assurance that it is in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart...*

While we agree and support this revision as providing flexibility to eliminate a requirement for potentially redundant supplier approval programs, it implies that the customer has knowledge of the importer's suppliers and the suppliers' programs to control identified hazards, which we do not support as a requirement of operations subject to parts 117, 507 or of this rule.

§ 1.504(b)(2) *Hazard identification Your analysis must include hazards that may be present in a food for any of the following reasons:... (iii) The hazard may be intentionally introduced for purposes of economic gain.* Notwithstanding our comment above, that importers should not be held responsible for a written hazard analysis of suppliers of fresh produce, we caution FDA that such identification should be limited to past experiences, not to some brainstorming of what could be done, thereby potentially informing disreputable suppliers of ways to obtain economic gain.

§ 1.506(a) *Use of approved foreign suppliers. You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the risk evaluation you conduct under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before using or distributing).* We agree and support this revision as providing flexibility to importers when necessary and on a limited basis. As a side note, we suggest that the term "unapproved" may be misleading – implying a supplier that does not meet the importer's requirements. Instead, we suggest descriptors such as "contingency" or "provisional" for such a supplier.

§ 1.506(d)(2) *When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you document your determination that, instead of such initial and annual onsite auditing, other supplier verification activities as set forth in paragraph (d)(1) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances in accordance with paragraph (c) of this section for the food and foreign supplier, based on the determination you made under § 1.505.* To the extent that FDA may interpret this provision as applying to fresh produce suppliers, we agree and support this revision as providing flexibility to importers, particularly in the case of emergency substitutions or new suppliers. This revision in no way decreases the moral and regulatory responsibility of importers to know their direct suppliers.

§ 1.506(d)(7) *Independence of qualified individuals. A qualified individual who conducts any of the verification activities set forth in paragraph (d) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.* We agree and support this provision, but we encourage FDA to make clear that this does not necessarily exclude the use of 1st party (i.e., internal) audits when the importer determines that such meet the requirements of this paragraph.

Notwithstanding the comments above, we remind FDA that our January 2014 comments include concerns not addressed in the Supplementary Proposal. We therefore append those comments to these, to ensure FDA has access to those considerations.

The members of United Fresh hope that FDA finds value in these considered comments, and we stand ready to clarify or assist FDA in these recommended changes to the proposed rule.

Respectfully submitted,

A handwritten signature in black ink that reads "David E. Gombas". The signature is written in a cursive style with a large, stylized initial "D".

David Gombas, Ph.D.
Senior Vice President
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