



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. Docket No. FDA–2011–N–0143; RIN 0910–AG64

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

United Fresh has long been the leader in continual enhancement of produce safety, bringing together food safety experts from across the industry to share understanding and drive process improvement, publish educational materials and best practice documents for multiple commodities and practices, and provide sound scientific input on potential policy actions by local, state, federal and international regulatory bodies.

United Fresh was a strong advocate for the Food Safety Modernization Act during its development. At its Board of Directors meeting January 20, 2007, United Fresh unanimously adopted the following guiding legislative principles for a food safety regulatory framework for produce:

- Produce safety standards must be consistent and applicable to all produce grown anywhere in the United States, or imported into the country.
- Produce safety standards must be mandatory, with sufficient federal oversight, in order to be most credible to consumers.
- Produce safety standards must allow for risk-based, commodity-specific food safety practices based on the best available science.

In preparing our comments on the Foreign Supplier Verification rule, we have implemented a widespread and intensive discussion with member companies with expertise at each stage of the produce supply chain from field to table. However, our comments can only address those broad issues that we have heard are of concern to the majority in our industry. We also encourage FDA to seriously consider the comments you receive from groups and associations that address additional specific concerns of foreign suppliers, importers and operations that handle fresh produce for consumption in the United States.

In order to ensure that each docket for FSMA's interlocking rulemakings are complete and that FDA can evaluate how the industry can be effectively and efficiently operate under the new FSMA rules, submitted to this docket as part of these comments are copies of United Fresh's comments on *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, Docket No. FDA-2011-N-0921; RIN 0910-AG35 and *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, Docket No. FDA-2011-N-0920; RIN 0910-AG36.

We appreciate FDA's efforts to meet the Congressional intent of the Food Safety Modernization Act, to hold food imported for consumption in the U.S. to the same food safety standards as food produced domestically. However, we believe that FDA has exceeded the Congressional mandate in several of the proposed requirements, as noted in our comments below. 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.

We recognize that FDA does not necessarily have regulatory jurisdiction over operations that export food for consumption in the U.S., and intends in the proposed Foreign Supplier Verification rule to hold U.S. importers responsible for oversight of their foreign suppliers. The primary intent of the rule is to ensure that foreign suppliers are in compliance with the relevant U.S. food safety regulations, whether that is Produce Safety or one of the Preventive Controls rules, and are not supplying adulterated or misbranded foods. However, we believe that FDA has gone beyond what is necessary in making such assurance, by mandating how importers are to verify compliance.

General Comments:

1. FDA proposes to define foreign supplier as "the establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature."

Many imported fruits and vegetables are not supplied by the entity that grows or harvests the food; rather, the importer receives them from a post-harvest handler/aggregator [a packer, shipper, or marketer] who may aggregate the produce from many growers. We agree that the importer should hold the aggregator accountable for meeting food safety regulatory requirements in its supply chain, but the importer should not be responsible for having specific detail information about each of the original growers. As this rule is proposed, either 1) the importer would need to have a foreign supplier verification program (FSVP) for each of his suppliers' suppliers, who often are unknown by the importer or may change without sufficient notice for the importer to implement a new FSVP; 2) the exporter would need to maintain a chain of custody separating each of his suppliers' produce, providing the importer with product only from growers for whom the importer has a FSVP; or 3) the importer would need to bypass the aggregator and purchase only from individual growers. Any of these potential methods of compliance would be extremely costly without assuring a higher level of safety, are far more complex than current industry practices, and are unlikely to have been considered in FDA's economic impact analysis.

Instead, we recommend that FDA include in the definition of foreign supplier the aggregator that exports the food, and require importers to verify that the aggregator is in compliance with the Produce Safety or Preventive Controls rule, as appropriate, and has procedures to verify that the produce the aggregator is exporting has been produced in compliance with the Produce Safety requirements. FDA may offer, in Guidance, recommendations to what such procedures may include, but should not mandate such procedures or mandate that the importer perform such procedures on its supplier's suppliers.

2. In our comments to the Preventive Controls for Human Food proposed rule, we recommended against inclusion of mandatory supplier approval programs. For that rule, all suppliers of ingredients must be in compliance with one or more FDA food safety regulations, making mandatory supplier approval programs redundant and an unnecessary cost. This includes ingredients that are imported in compliance with the Foreign Supplier Verification rule. The Foreign Supplier Verification rule is already a mandatory supplier approval program for direct exporters to the U.S., and we reaffirm here that we do not believe that supplier approval programs of supplier's suppliers should be mandated, even when the direct exporter, the importer and subsequent users of the food do not have direct control over potential hazards.
3. In § 1.512(b), FDA proposes modified requirements for very small importers or for importing food from a very small supplier, limiting requirements to compliance with §§ 1.502 (What foreign supplier verification program (FSVP) must I have?), 1.503 (Who must develop my FSVP and perform FSVP activities?), 1.504 (What review of a food and foreign supplier's compliance status must I conduct?), 1.509 (How must the importer be identified at entry?) and other modified requirements in § 1.512(b)(3)-(6). This exemption affects a vast number of foreign operations and particularly those with limited food safety resources. There is likely to be an unintended consequence of foreign supplier and importer operations that do not want to comply manipulating their size so that they do not need to comply, particularly at the proposed size of very small importers or foreign suppliers ("whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$500,000, adjusted for inflation").

We respectfully submit that food safety hazards are independent of the size of the operation supplying or importing the food and, if there is a bias, that smaller operations are more vulnerable than large. The produce industry has seen several examples of foods imported from very small operations that have caused significant illness outbreaks (notably the very small foreign operation that FDA believes was the source of the *Salmonella* Saintpaul outbreak of 2008). Therefore, we recommend that FDA eliminate this dichotomy of requirements for importers. If FDA believes that the modified requirements described in § 1.512 are sufficient to evaluate the safety of imported foods, then the rule should be limited to these requirements regardless of the size of the importer or the foreign supplier. If FDA believes that one or more of the requirements excluded for very small operations are necessary to evaluate the safety of imported foods, then they should be included for importers of any size.

4. In our comments on the proposed Produce Safety rule, we argued against FDA's proposed exemption of grower operations with annual food sales less than \$25,000 (recommending instead that FDA mandate size-appropriate requirements that provide the same level of public health protection). While the proposed Foreign Supplier Verification rule is silent on such an exemption, a fair interpretation of the Congressional intent – that domestic and foreign operations be held to the same standards – would be

that foreign operations that meet that definition would also be exempt. Hence, if an importer is sourcing directly from a grower/shipper with annual food sales of less than \$25,000, then that supplier would be exempt from the requirements of the Produce Safety rule. We do not believe this meets the Congressional intent for food safety, nor can the produce industry support such an exemption. However, requiring importers to hold such foreign operations to standards that domestic operations are not, invites a future WTO challenge. Therefore, we reaffirm our belief that produce operations, foreign and domestic, not be exempted on the basis of size; rather, that FDA include size appropriate requirements in the Produce Safety rule for such operations, foreign and domestic.

5. In the proposed definition of manufacturing/processing, FDA says that “For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding”. As we strongly recommended in our comments to the Produce Safety and Preventive Controls proposed rules, FDA’s definition of farm and farming activities is too limited, and operations, including foreign suppliers, that only perform activities on raw, intact produce and which result in products that are still raw, intact produce, should be covered by requirements of the Produce Safety rule.
6. In § 1.501(a), FDA proposes that “Except as specified otherwise in this section, the regulations in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.” No exemptions are listed for rarely consumed raw, which is inconsistent with FDA’s proposed Produce Safety regulation. In our comments on the proposed Produce Safety rule, we recommended that such exemptions be removed from the rule, replaced with modified requirements consistent with a hazard analysis appropriate for products intended to be further processed before consumption. Therefore, we support FDA’s omission of such exemption in the Foreign Supplier Verification rule and again recommend that the Produce Safety rule do likewise.
7. § 1.505(a) requires importers to “determine the hazards, if any, that are reasonably likely to occur with the food and, for each, the severity of the illness or injury if such a hazard were to occur.” While this requirement may be consistent with FDA’s proposed Preventive Controls rules, this exceeds the requirements of the proposed Produce Safety rule. In the Produce Safety rule, FDA proposed to limit the risks covered in the rule to microbiological, not chemical or physical, having performed their own hazard evaluation for produce sourced in the U.S. In the Foreign Supplier Verification rule, FDA proposes to require importers’ hazard analyses to go beyond microbiological risks, apparently requiring importers to evaluate potential chemical and physical hazards in fresh produce exported to the U.S. As noted above, this potentially requires foreign fresh produce growers to have and comply with food safety plans that exceed requirements of domestic operations, inviting a WTO challenge. Meanwhile, we are unaware of U.S. outbreaks due to chemical or physical hazards linked to fresh produce, whether domestic or foreign, and would therefore conclude that chemical and physical hazards from imported fresh produce are equally unlikely to occur. So, while an importer may choose to evaluate potential chemical and physical hazards from a foreign supplier, we again recommend that FDA limit an importer’s requirements to verifying that the direct foreign supplier is in compliance with the relevant FDA regulation, and not require an importer to go beyond requirements of domestic operations. Further, if FDA believes that the requirements in the Produce Safety rule are adequate for domestically sourced fresh produce, then the same should be true for imported produce, and importers should be exempted from the requirements of § 1.505 for produce imports subject to Produce Safety. We agree that FDA may include a provision in the rule, allowing FDA to revoke

such exemption should future events demonstrate an expanded hazard analysis of fresh produce suppliers is necessary.

8. In § 1.505(c), FDA proposes that the importer's hazard evaluation must consider 9 items, including the effect of the "condition, function, and design of the foreign supplier's establishment and equipment". While the other 8 items address potential hazards that can be evaluated by reviewing a supplier's food safety plans and records, this item cannot. Rather, this cannot be evaluated without an onsite inspection of the operation. Therefore, while § 1.506 allows for importers to conduct verification by sampling and testing or by review of a foreign supplier's food safety records, the only practical manner of assessing potential hazards from an operation's facility and equipment is by onsite audit. Again, we support the provision in 1.505(e) which explicitly exempts produce importers from performing a hazard analysis of microbiological risks, we encourage FDA to limit importers' requirements to verification that direct suppliers are in compliance with the relevant regulation and to not require importers of fresh produce to perform a hazard analysis beyond the scope of the Produce Safety rule, and to offer the "how to comply" instructions in § 1.505 as recommendations to fresh produce importers evaluating foreign suppliers who must comply with the Preventive Controls rule.
9. In § 1.506, FDA offers two options for "requirements for hazards not controlled by you or your customer". Option 1 requires importers of raw fresh produce "before importing the fruit or vegetable from the foreign supplier and at least annually thereafter, [to] conduct or obtain documentation of an onsite audit that examines the control of microbiological hazards associated with the fruit or vegetable." Option 2 appears to be more flexible, allowing "one or more of the verification activities listed in paragraphs (g)(1)(i) through (iv) of this section", only one of which is an onsite audit. However, as noted in our comment 8 above, other requirements of the rule would make onsite audits obligatory and prerequisite. As described in our comment 1, above, if FDA intends that importers perform such verifications at the grower level, this requirement will have a dire impact on importers' access to foreign suppliers and foreign suppliers' access to U.S. markets.

In both options, FDA allows for certain hazards "any other procedure that you have established as being appropriate based on the risk associated with the hazard". We support allowing all importers, including importers of fresh produce, this option for verifying their suppliers' compliance with the relevant regulation.

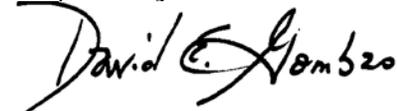
Additional Specific Comments

- § 1.500: "*Lot* means the food produced during a period of time indicated by a specific code." As we recommended in our comments to the proposed Preventive Controls for Human Food rule, lot can be defined by criteria other than time. FDA's proposed definition appears to ignore other potential definitions, e.g., products with common characteristics, such as origin, variety, type of packing, packer, consignor or markings. Also, multiple "lots" can be produced during the same time (e.g., different processing lines) but with different lot designations. We recommend a more flexible, robust definition, such as "a body of food designated by the facility with common characteristics, e.g., origin, variety, type of packing, packer, consignor, markings or time of harvest, packing or processing, which is separable by such characteristics from other bodies of food."

- § 1.500: "...a *qualified individual* must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and implement a food safety system." It is unreasonable to expect all foreign suppliers to travel to the U.S. to complete such training. It is also unlikely that the FDA-recognized training will be available in all languages of operations and in all countries exporting food to the U.S. Third, there are food safety training courses offered outside the U.S. that provide adequate training with a curriculum different from that expected to be recognized by FDA. However, there are also courses purporting to provide food safety training which are, in fact, inadequate. Therefore, FDA must provide a process by which foreign training can be recognized as equivalent or adequate. FDA must implement such a process in time for foreign operations to become compliant.
- § 1.504 "You must continue to monitor and document the compliance status as long as you import the food from the foreign supplier." As written, "continue" can be interpreted as lot-by-lot, monthly, annually or some other frequency. While we support the requirement, we recommend that FDA include some minimum acceptable frequency that can be implemented in a practical manner; e.g., initially, and annually or as new information becomes available.
- § 1.510(a) "You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP." The rule is silent on the position of the qualified individual who must perform this requirement. We agree and support that the importer should be at liberty to decide who must be qualified and authorized to sign.

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,



David Gombas, Ph.D.
Senior Vice President
Food Safety and Technology