



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: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food – Supplementary Proposal.
Docket No. FDA-2011-N-0920; RIN 0910-AG36**

The United Fresh Produce Association (“United Fresh”) appreciates the opportunity to comment on the supplementary proposal to the proposed regulation *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (“Preventive Controls 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.

Off-farm Operations Regulated Under Preventive Controls Rule

In our 2013 comments to the proposed rule, we said that FDA has inappropriately grouped facilities that only pack and handle raw agricultural commodities that are fresh produce together with food processing facilities, which are the actual focus of the proposed rule. We understand that FDA intends a sharp division between “facilities” subject to Preventive Controls and “farms” subject to proposed part 112 Produce Safety based on the registration regulations developed under the Bioterrorism Act, but this distinction puts an undue regulatory burden on operations that only hold, pack and ship fresh produce, the same as farming operations subject to Produce Safety, but whose primary purpose is not growing or harvesting fresh produce. In the November 13, 2014 public meeting on the supplementary proposals, FDA heard more public comments concerning this artificial distinction than on any other content of this proposed rule; i.e., that establishments engaged solely in traditional harvesting, holding, or packing activities associated with a covered raw agricultural commodity should not be subject to Preventive Controls, but instead should be subject to the Produce Safety rule, regardless of physical location, ownership or legal ties to an operation devoted to the growing and harvesting of fresh produce.

FDA has made clear in public comments that this regulatory distinction between on-farm and off-farm produce handling operations is only because of the statutory language in the

Food Safety Modernization Act, not because of any hazard assessment or public health risk requiring a different regulatory approach. While FDA has suggested publicly that the requirements would be similar under the two rules, we respectfully disagree. As examples, off-farm packinghouses, cooling and storage facilities subject to part 117 would be required to have, among other things, a written hazard analysis that goes beyond the microbiological hazards in the Produce Safety rule, written preventive controls to include written sanitation and allergen control measures, written monitoring and corrective actions, validation of process controls, a written recall plan, environmental and product testing requirements and a written supplier approval program, none of which are required of a farm under part 112. Further, such operations would be required to comply with part 117 one year earlier than similar sized operations under part 112. The differences in regulatory and economic burden are obvious, and would perpetuate beyond the implementation of these rules.

The supplementary proposal appropriately extended the definition of farm in subpart § 1.227 to include packing or storing of produce not grown on the same farm, and extended the definition of farming activities to include activities performed for the safe or effective storage or packing of that food and activities performed as a practical necessity for the distribution of that food. The definition has been further extended to include “drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and (B) Packaging and labeling raw agricultural commodities”. We agree that such activities can be adequately regulated on a farm under the Produce Safety rule, and there is no scientific rationale for the same activities to require a different regulatory approach simply because the operation is located away from same general location of the farm where the produce is grown, or is not under the same ownership, or is not devoted to the growing and harvesting of raw agricultural commodities, or is otherwise required to be registered under a different regulatory requirement.

Consequently, we again respectfully request that FDA remove this distinction in the Produce Safety, Preventive Controls for Human and Animal Foods, Foreign Supplier Verification Programs and in any other relevant rules where facility registration is the sole distinguishing requirement, and we suggest the following two options as ways FDA can codify that off-farm operations that perform the same functions as on-farm packing and holding operations are covered by the same rule:

- 1) Add a new paragraph to § 112.4 that extends the rule to registered establishments that perform only holding, storing and packing activities of covered produce consistent with covered activities performed by a farm, but that do not perform growing or harvesting. As FDA has not responded to our objection in our 2013 comments to the concept of a “farm mixed-type facility”, which may be subject to both Produce Safety and Preventive Controls requirements, we now suggest that FDA can use the definition of a mixed-type facility to include such off-farm operations under Produce Safety; i.e., “an establishment that engages in both activities that are exempt from registration...and activities that require the establishment to be registered.” However, such a paragraph should not restrict establishments that, because of other food handling activities, choose to follow part 117.

Or,

- 2) Add a new subpart to part 117 that permits registered establishments that only hold, store or pack raw agricultural commodities, consistent with the relevant § 1.227 definitions of holding and packing, to meet their obligation by compliance with the subparts of part 112 that apply to those activities, such as subparts C, D, K, L and O.

Either approach makes irrelevant whether an operation is required to register under 21 CFR part 1, subpart H, and codifies that operations that perform the same covered activities on the same covered commodities are to be regulated under exactly the same requirements.

We believe both options to be within the Secretary's existing authority under the Federal Food, Drug, and Cosmetic (FD&C) Act "to promulgate regulations for the efficient enforcement" of the Act (FD&C Act § 701(a); 21 U.S.C. § 371(a)). Should the agency determine that it is unable to adopt either of these two solutions because of the structure of section 415 of the Act, 21 U.S.C. § 350d, we respectfully request that FDA explicitly acknowledge that it is a statutory restriction on its ability to exclude such establishments from the definition of facility despite the absence of a scientific rationale for the same activities to require a different regulatory approach simply because the operation is located away from same general location of the farm where the produce is grown, or is not under the same ownership, or is not devoted to the growing and harvesting of raw agricultural commodities, or is otherwise required to be registered under a different regulatory requirement.

Definition of Farming Activities

In our 2013 comments, we expressed concern that the definitions of farming activities proposed by FDA, including harvesting, holding and packing, were too limited. We commend FDA on revising the definitions to make clear that these include activities performed for the safe or effective storage or packing of that food and activities performed as a practical necessity for the distribution of that food, and specifically include activities such as packaging, labeling, drying/dehydrating, and field coring. We agree that the demarcation should be activities that transform a raw agricultural commodity into a processed food. However, we are concerned that there remains an opportunity for misunderstanding that examples of traditional farm activities performed on raw agricultural commodities can also include culling, conveying, sorting, waxing, and shipping, and storing can include crop maintenance activities like fumigation, pest control, sprout inhibition, fogging, other chemical treatments (e.g., treatment with 1-methylcyclopropene (1-MCP) to inhibit ethylene recognition and enzymatic browning) and atmosphere control for ripening or ripening inhibition. In short, any normal handling, holding or packing activity performed on raw, intact produce, or treatment with packing, cooling or holding aids that result in no significant change in the hazard analysis for the product, should be considered consistent with the above definitions and do not create a "processed" product. To avoid such misunderstanding, we recommend that such examples be specified in Guidance and as not exhaustive. We further recommend that activities that may be performed on either raw agricultural commodities as a "farming activity" or on processed foods be clearly explained in Guidance, so as not to risk misinterpretation that such activities necessarily make a raw agricultural commodity a "processed" food.

Exclusion of Fresh and Fresh-cut Produce from Mandatory Product Testing

In our 2013 comments, United Fresh agreed with the Office of Management and Budget's (OMB's) decision to exclude from the rule any mandatory microbiological testing of raw or finished product. While such provisions may appear reasonable to operations that process certain FDA-regulated foods, imposing such requirements on fresh produce is not scientifically valid, creates an unnecessary economic hardship, and may increase food safety risk.

Currently, there is no scientific validity to any economically feasible sampling scheme to detect anything but gross contamination in fresh or fresh-cut produce, and FDA has

recognized that attention to GAPs and GMPs is a more reliable approach to preventing gross contamination. Further, raw materials that are raw agricultural commodities are individual entities; testing of one piece of produce is not likely to be representative of others in that "lot". Even if a "positive" sample is found for an indicator or pathogen, such a result provides no information about the existence, level or extent of contamination of other produce in the same lot. Therefore, testing raw agricultural commodities is not likely to provide useful information.

Rather than repeat our concerns with mandatory product testing, we have attached, for the record, our November 2013 comments on this subject. However, we conclude by strongly objecting to mandatory product testing and instead, taking notice that FDA intends such testing to be performed "as appropriate to the facility, the food, and the nature of the preventive control", recommend that any product testing be a voluntary decision of the operation, directed by their hazard analysis and food safety plan.

Exclusion of Mandatory Environmental Testing

In our 2013 comments, United Fresh agreed with OMB's decision to exclude from the rule any mandatory environmental testing. While United Fresh agrees that operations vulnerable to harborage and product contamination by pathogens like *Listeria monocytogenes* should implement effective facility and equipment monitoring and control programs, not all fresh produce handling operations will be susceptible to such harborage. For such operations, mandatory environmental monitoring would be a wasteful economic burden without public health benefit. However, we agree that environmental monitoring can be an effective preventive control for operations vulnerable to environmental contamination of product, if so determined in the operation's hazard analysis. As the target organisms, locations, procedures, and reactions to environmental monitoring will be facility specific, we urge FDA to provide maximum flexibility in this requirement, including exempting operations when their hazard analysis appropriately concludes that there is no foreseeable risk. However, we encourage FDA to provide, in Guidance, examples of where and how such monitoring may be useful and used.

Exclusion of Mandatory Supplier Approval Programs

In our 2013 comments, United Fresh agreed with OMB's decision to exclude from the rule a mandatory supplier approval program. While United Fresh recommends that operations only use suppliers who follow GAPs and, as appropriate, GMPs and Preventive Controls, it would be an unnecessary economic burden to require special programs. Because of unforeseeable events (e.g., weather events, late harvests, poor quality, food safety issues with the anticipated lot), fresh produce buyers frequently need to purchase raw materials from substitute suppliers. Requiring pre-approval, let alone verification, of substitute suppliers may prevent companies from meeting production requirements and filling customer orders. Further, such a requirement will be unnecessary after full implementation of proposed parts 112 and 117, when lawful suppliers, both domestic and imported, will already be following necessary food safety practices.

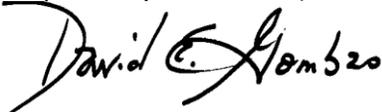
We are particularly concerned with the implications of paragraph § 117.136(b)(2), i.e., "In determining and documenting the appropriate verification activities, the receiving facility must consider the following:... (2) Where the preventive controls for those hazards are applied for the raw material and ingredients – such as at the supplier **or the supplier's supplier**" [emphasis added]. In the fresh and fresh-cut produce industry, the safety of incoming fresh produce is the responsibility of each step in the supply chain, and there can

be multiple steps between the farm on which the produce was grown and the facility purchasing it, the identities of those steps typically being proprietary. Therefore, an operation purchasing fresh produce cannot know, with certainty, the programs implemented by their supplier's suppliers or their supplier's suppliers' suppliers. Instead, they can only request and review the procedures by which their immediate supplier approves their immediate suppliers. We therefore recommend that FDA provide clear flexibility regarding any requirements for the contents and performance of an operation's supplier approval program.

Paragraph § 117.136(c)(2)(i) requires that "when a hazard in a raw material or ingredient will be controlled by the 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, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter." As noted above, this can be an egregious burden for purchasers and suppliers of fresh produce. Therefore, we commend FDA, and support inclusion of paragraph § 117.136(c)(2)(ii), that clarifies "the requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled."

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, flowing style.

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