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Dockets Management Branch (HFA-305)
Food and Drug Administration
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<http://www.regulations.gov/>

**Re: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Supplemental Notice of Proposed Rulemaking.
Docket No. FDA-2011-N-0921 RIN 0910-AG35**

The United Fresh Produce Association ("United Fresh") appreciates the opportunity to comment on the supplemental proposal to the proposed regulation *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* ("Produce Safety 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.

We commend FDA for recognizing many of the issues raised in response to the 2013 proposal, either through comments submitted to the docket, during public meetings, or during FDA's extensive visits to fresh produce operations around the country, resulting in this supplemental proposal. However, while the supplemental proposal better addresses some of these issues, we remain concerned that FDA's proposed rule still fails to follow the legislative intent of the Food Safety Modernization Act (FSMA) to provide for a true risk-based approach that recognizes the diversity of the fruit and vegetable industry. As we noted in our 2013 comments, FSMA was clear in directing FDA to take into account differences in risk profile among commodities and practices:

"(a)(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based on known risks which may include a history and severity of foodborne illness outbreaks."

The supplementary proposal is silent on this very important part of the statute. While we commend FDA for recognizing that there are no "high risk" commodities – only practices that can elevate the risk of contamination – the rule fails to recognize the potential for many fresh produce commodities to be "low risk"; i.e., having a lower potential to become a vehicle of foodborne illness because of inherent properties. Science has not yet revealed

whether or how commodities that have never been linked to a foodborne outbreak may be resistant to supporting pathogens at a public health level of risk, but the rule ignores this potential, maintaining a “one size fits all” approach to commodities not exempted. The rule proposes only “variance” as a means of adopting such future science, and the rule remains vague on the requirements regarding variances except to limit their submissions to state and foreign governments. We encourage FDA to consider codifying an approach to include modified requirements for commodities scientifically demonstrated to be low risk. But, if FDA determines that such can only be accomplished by variances, we repeat, for emphasis, that variances to any part of the rule should be allowed to be submitted by any credible entity, not just government agencies. Further, submissions of variances should not be made onerous by holding variances to a higher standard of scientific validation than what FDA has used in setting the standards in the rule itself.

We respectfully remind FDA, by attaching our November 2013 comments again for FDA’s consideration, that issues such as in the comments above have not been addressed in the supplementary proposal, but remain significant concerns to the fresh produce industry.

That said, we will limit our comments below to the supplementary proposal.

§ 112.3 Definitions

We commend FDA in redefining “farm” to include packing of produce not grown on the same farm, and by expanding the definitions of holding and packing to include “activities performed incidental to storage [or packing] of a food (e.g., 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 supplementary proposal expressly includes packaging and labeling “when these activities do not involve additional manufacturing/processing”, but we remain concerned that activities not expressly identified as covered activities may be interpreted as processing, invoking coverage under proposed part 117. Inhibition of sprouting, fumigation, artificial ripening or ripening suppression through ethylene control, and controlled atmosphere storage (bulk, not modified atmosphere packaging) are additional examples of holding activities that are performed by farms on certain covered commodities but are not activities that involve additional manufacturing/ processing. “Clean and core” and similar in-field practices for trimming fresh produce should be included in the Produce Safety rule as examples of harvesting, consistent with the supplementary proposal for Preventive Controls for Human Food. There undoubtedly remain other activities that are performed on raw agricultural commodities by farms that, if not expressly described, may be interpreted inappropriately as manufacturing/processing. We therefore encourage FDA to include in the rule as broad a definition of farm and farming activities as possible, relegating a list of specific activities to Guidance.

§ 112.4 Who is subject to the requirements of this part?

As in the 2013 proposed rule, this subpart limits covered operations to a “farm or farm mixed-type facility”, where the definition of a farm is “an establishment...devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both”. This definition of farm precludes establishments which perform the same packing and holding activities as farms but do not perform growing or harvesting. As we noted in our 2013 comments, we agree that operations that process/manufacture fresh produce, e.g. a fresh-cut operation, should be covered by part 117, Preventive Controls for Human Food. However, the risk profile of intact produce packed in a standalone packinghouse or stored in an off-farm warehouse is no different than at an on-farm packing shed or storage facility.

While FDA has suggested publicly that the requirements would be similar under the two rules, we respectfully disagree. As examples, off-farm packinghouses 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 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.

If FDA agrees with our assertion that such establishments should be regulated equally, we would like to suggest the following two options to codify that on-farm and off-farm operations that perform the same functions are covered by the same rule:

1) Add a new paragraph to § 112.4 that extends the rule to registered establishments that perform holding, storing and packing activities on covered produce, consistent with covered activities performed by a farm, but that do not perform growing or harvesting. We suggest that FDA may extend the definition of a "mixed-type facility" to such off-farm operations; i.e., "an establishment that engages in both activities that are exempt from registration...and activities that require the establishment to be registered." 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 that are fresh produce 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.

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.

§ 112.44 and 112.45 Testing Of Agricultural Water

Revisions proposed to the metrics and frequencies for water testing demonstrate that FDA has recognized the broad-based concerns that the original proposal engendered. However, the revised requirements are very confusing, the testing frequencies still put operations that use surface water at an unfair disadvantage, and codifying agricultural water quality standards based on generic *E. coli* levels is still arbitrary and not food-safety based.

We commend FDA on proposing an opportunity for growers to implement a pre-harvest and/or post-harvest interval after final direct contact with agricultural water, to allow for a "die-off" of *E. coli*. However, while emphasizing testing near to harvest when the quality of the water matters most, and decreasing the testing burden on operations from the original proposal, the rule still proposes that open water sources need to be tested 20 times

in the first 2 years, and five times a year thereafter. The proposal also includes a complicated approach of geometric means and, now, statistical threshold values. We respectfully submit that this approach is overly complicated, and testing water sources more often will not make them safer, particularly those water sources over which the responsible party has no control.

Instead, we propose a simpler, modified approach to testing:

- 1) Only those water sources likely to come into contact with the harvestable portion of covered produce within X days of harvest (Covered Water Source) should be subject to water testing requirements. We agree with FDA that testing of water sources when agricultural water is used during growing activities is only necessary when there is a reasonable likelihood of direct water contact with the harvestable portion of covered produce. However, this principle should only apply when there is a reasonable likelihood that the produce will become unsafe as a result of the direct water contact. In consideration of the die-off provision, we propose that only a Covered Water Source should be subject to water testing requirements, with the number X open for discussion and consistent with the die-off provision.
- 2) No water testing is necessary if the Covered Water Source is municipal (and municipal records of water quality are available) or treated (and records of chemical testing are available), as currently proposed by the FDA.
- 3) Minimum testing frequencies should be consistent for all Covered Water Sources. We agree with the FDA that an operation should initially test the quality of each Covered Water Source to determine its baseline quality. We propose that the initial number of tests required to establish a baseline quality for all Covered Water Sources should be at least four times during the growing season or over a period of 1 year, using a minimum total of four samples. There should be no difference between minimum testing frequencies for surface and groundwater sources.
- 4) Annual testing frequencies of all Covered Water Sources should be a minimum of one sample annually, regardless of whether the source is ground or surface water. FDA has proposed 410 generic *E. coli* per 100 mL as a maximum acceptable level. Recognizing that that number is open for discussion (e.g., our prior recommendation to use the Codex recommendation of 1000 generic *E. coli* per 100 mL), if baseline testing demonstrates that a Covered Water Source meets this level, whether groundwater or surface, no mitigation is needed and an operation may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. An operation should be at liberty to perform more testing to demonstrate that any exceedances are outlier values or to demonstrate that corrective actions have been effective, but there should be no difference between minimum testing requirements for surface and groundwater sources.
- 5) Four mitigating actions are available if testing demonstrates an exceedance of the maximum acceptable level. An operation can, as proposed in the supplementary proposal, 1) take corrective action to bring the water into compliance by removing the source of *E. coli* and demonstrate compliance by retesting, 2) discontinue using the source, 3) treat the water to bring it into compliance or 4) implement a preharvest or post-harvest interval to allow for sufficient *E. coli* die-off after the last direct water contact to meet the standard. However, we believe that there is an *E. coli* level above which the water quality is inappropriate for direct water contact and the preharvest die-off option should not be used. We propose a maximum preharvest interval allowance of 4 days, to correct water that has up to 2 logs more than the maximum acceptable level. The annual testing with a minimum of one sample collected during a time period as close as practical to harvest should be used to demonstrate the Covered Water Source does not exceed this level.

Further, we all agree that science has not yet provided “the right answer” to the test organisms, the testing frequency or the testing methodology to demonstrate that the water is “safe” to use, similar to FDA’s conclusion regarding a safe preharvest interval for application of untreated biological soil amendments of animal origin (see below). Our goal at this time should be for growers to “know their water”, using generic *E. coli* as a poor but best available indicator. So, until a better answer is revealed, we continue to recommend that these standards reside in Guidance.

None of the above recommendation should limit an operation from implementing an alternative or variance water quality verification procedure for which they have a scientific justification.

§ 112.56 Biological Soil Amendments of Animal Origin

We commend FDA for recognizing that compost that has been treated and verified to be within the standards proposed for the identified microorganisms does not pose a reasonably foreseeable threat to food safety and does not require a minimum application interval. We also commend FDA for recognizing that a 9 month minimum application interval for untreated biological soil amendments of animal origin is arbitrary and not science-based. We also commend FDA for committing to sponsor research with which to identify science-based control measures for such soil amendments, and for recognizing that such may take years to develop. However, use of the term “reserved” in § 112.56(a)(1)(i) has created confusion as to what FDA will consider a minimum application interval in the meantime.

In the preamble to the supplementary proposal, FDA has stated an intent to not “take exception to the continuation of adherence to the National Organic Program (NOP) standard”, as described in 7 CFR 205.203, despite recognition that the NOP standard is not based on a food safety goal, and there is published research suggesting that the NOP preharvest interval standards may not be sufficient to assure demise of human pathogens. Nevertheless, that standard has been used extensively across a broad range of crops and a broad range of regions, and FDA has not reported any organic produce-related outbreaks attributable to manure use managed under the NOP standard.

We therefore support FDA establishing the NOP standard for manure use as a minimum interim standard, until such time that science provides a better answer.

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,



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