

April 19, 2016

Michael Taylor  
Deputy Commissioner for Foods  
and Veterinary Medicine  
Food and Drug Administration  
10903 New Hampshire Ave  
White Oak Building 1  
Silver Spring, MD 20993

Dr. Stephen Ostroff  
Chief Scientist  
Office of the Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
White Oak Building 1  
Silver Spring, MD 20993

Dear Commissioner Taylor and Dr. Ostroff:

On behalf of the undersigned associations representing the overwhelming majority of producers and distributors of fruits and vegetables consumed in the United States, thank you for FDA's hard work, dedication and transparency in implementing the Food Safety Modernization Act (FSMA). As you know, food safety is a top priority for our industry, and we have worked collaboratively with Congress and the Agency for many years to formulate, pass and ultimately implement the FSMA legislation.

As our industry now shifts into our education and compliance phase with the new rules, we want to continue that close collaboration with you to ensure that we are achieving the vision and food safety goals we all share. It is in that spirit that we want to bring to your attention several unintended consequences of the new rules, and seek a meeting to discuss potential solutions.

### **Conflicting Standards for Similar Facilities Subject to Different Rules**

As Commissioner Taylor has recognized in the past, one of the unintended effects of the FSMA legislation itself has created a conundrum for FDA in regulating identical facilities that pack or handle raw agricultural commodities sometimes under the Produce Safety Rule (PS) and sometimes under the Preventive Controls (PC) Rule. This anomaly is due to FSMA's categorization of facilities that are required to register with FDA under the Bioterrorism Act as falling under the PC rule. As FDA has struggled with trying to write science-based regulations, the Agency has formulated a strained bifurcation of facilities as either on-farm or as secondary activities farms. Although identical facilities as far as food safety risks, "on-farm" facilities fall under the PS Rule while most "off-farm" facilities fall under the PC Rule. We estimate that nearly 5,000 facilities across the country fall into this latter category, requiring a vastly different regulatory structure under the PC Rule.

While we appreciate that FDA representatives have repeatedly told the industry and public meetings that they intend to write guidance that specifies these off-farm RAC facilities should follow the same standards as the PS Rule, such guidance has not been forthcoming and yet the September 19, 2016 PC Rule compliance deadline is looming. And, while such guidance would indeed be helpful, we believe a technical fix in the underlying FSMA provision is truly the appropriate way to correct this error. We recognize that any legislative fix must garner widespread support from all stakeholders – especially FDA – as well as consumer health advocates. While we have explored different potential options to correct this unintended effect of the law, we know that a final solution will require all of our support. Commissioner Taylor, as we've discussed this conundrum in the past, we hope you can share our mutual concerns with Dr. Ostroff and our continuing dedication to the highest level of food safety and public health.

Recognizing that such a solution will also require some time, we request near-term relief in enforcement of the PC Rule for these specific facilities. Let us share two examples of why the September 2016 deadline is inappropriate for these facilities. As you know, the PC Rule requires the presence of trained Preventive Controls Qualified Individuals (PCQI) at facilities. However, the current curriculum developed by the Food Safety Preventive Controls Alliance far exceeds requirements for what is needed to address food safety issues that FDA has deemed appropriate for fresh produce packinghouses and RAC warehouses under farm ownership. While we are training our industry's fresh-cut processors with this curriculum as quickly as possible, the course would create confusion and even inappropriate food safety steps if applied to RAC packinghouses and warehouses.

Finally – a word about the real world in which our members operate. If the Agency does not grant some relief in compliance dates for these facilities, we can be certain that our retail and foodservice customers will demand their suppliers be in “full compliance” with the regulation. Even if FDA representatives communicate that guidance or a new curriculum for these facilities is coming, our buyers will not grant leeway without a formal adjustment of the compliance date. And, just to be clear, we are NOT asking for a change in the compliance date for fresh produce processing facilities, but only those off-farm RAC facilities.

### **Delay in Produce Safety Training Curriculum**

A second issue of significant concern is the delay in FDA's approval of the Produce Safety Alliance's curricular to train operations under the PS Rule. We stand ready to begin training growers throughout our industry, but are stymied without an approved curriculum for the PS Rule. The current estimate for release of an approved curriculum is late 2016, leaving little time for the extensive training of thousands upon thousands of individuals who will need training. Depending upon

the final roll-out of PSA training, we ask the Agency to consider a commensurate delay in compliance dates for the PS Rule to allow adequate timing for training.

### **Request for Meeting**

With Commissioner Taylor soon departing the Agency, we would like to request a meeting with the two of you together. We believe it is important that we maintain the continuity of dialogue, trust and transparency between our many organizations and FDA.

We would hope to discuss the specific issues raised in this letter, as well as any other topics of potential benefit in our continuing dialogue between the Agency and the produce industry. We thank you in advance and look forward to meeting with you soon.

Sincerely,

United Fresh Produce Association  
American Mushroom Institute  
National Potato Council  
National Watermelon Association  
Produce Marketing Association  
U.S. Apple Association  
Fresh Produce Association of the Americas  
California Citrus Mutual  
California Fresh Fruit Association  
Grower-Shipper Association of Central California  
Western Growers  
Florida Fruit and Vegetable Association  
Florida Tomato Exchange  
Georgia Fruit and Vegetable Growers Association  
Idaho Grower Shippers Association  
Idaho Potato Commission  
New York Apple Association  
Texas Citrus Mutual  
Texas Vegetable Association  
Texas International Produce Association  
Northwest Horticultural Council  
Washington State Potato Commission