

February 21, 2017

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **“Classification of Activities as Harvesting, Packing, Holding, or Manufacturing / Processing for Farms and Facilities; Draft Guidance for Industry” [Docket No. FDA–2016–D–2373]**

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) and United Fresh Produce Association, together with the California Leafy Green Products Handler Marketing Agreement, Canadian Produce Marketing Association (CPMA), Northwest Horticultural Council, and Western Growers, respectfully submit the following comments to the draft FDA guidance entitled, *“Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry”* (Docket No. FDA–2016–D–2373).

We first would like to acknowledge and thank FDA for its efforts in developing this draft guidance to industry to assist businesses in determining whether the activities that they perform are or are not within the FDA “farm” definition.

However, there are still very serious produce industry concerns that the regulatory lines of coverage are clouded between the Produce Safety Rule and Preventive Controls for Human Foods Rule are unclear because of the criteria that FDA has chosen to define a “farm” (i.e., primary production farm and secondary activities farms). The FDA definition of “farm” is extraordinarily complex relying on numerous and different factors/criteria to define these two “farm” types. Criteria such as “majority of interest,” “ownership,” “under one management” and “in one general (but not necessarily contiguous) physical location” remain undefined and are ambiguous and impossible for entities covered by these FSMA rules to interpret without consulting FDA.

This DRAFT guidance issued by FDA acknowledges: *“It is not directed to interpreting other aspects of the “farm” definition (such as an interpretation of “under one management” or “in one general (but not necessarily contiguous) physical location”), or other definitions in our regulation for Registration of Food Facilities (such as “retail food establishment”), even though these other aspects and definitions may be relevant to determining whether your business must register as a food facility and the applicability of other requirements, such as those in 21 CFR Parts 112, 117, and 507. Certain aspects of the “farm” definition, such as “under one management” and “in one general (but not necessarily contiguous) physical location,” are very fact-specific, and therefore*

we are not issuing guidance focused on these topics at this time but are instead addressing them on a case-by-case basis.

This acknowledgment by FDA means that an extraordinarily large number of firms will need to consult with FDA on a case-by-case basis for assistance in helping them determine whether their produce business is or is not a “farm” covered by the produce safety rule or is a food facility covered under the Preventive Controls for Human Foods Rule. This is simply unworkable for businesses and overly burdensome for the agency.

The DRAFT FDA guidance *“Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry”* is intended to clarify when specific activities do and do not fall within the FDA definition of “farm.” The mere fact the FDA has felt compelled to issue such clarifying guidance illustrates the complexity, unsuitability and practical unworkability of the “farm” definition.

We acknowledge that FDA has worked hard and attempted to construct a workable definition of “farm,” but it has become so convoluted and unclear that it is simply impracticable for businesses to understand and implement with confidence. This inability and uncertainty by covered firms to easily understand if they are or are not a “farm” has created fear and anxiety of regulatory jeopardy in the regulated produce business community.

We also acknowledge that FDA’s attempt to more broadly define a “farm” was intended to address the Food Safety Modernization Act statutory requirement that registered food facilities are to be regulated by the preventive controls for human foods regulation. However, FDA’s interpretation of this FSMA statutory requirement set up a situation whereby some on-farm produce packinghouse operations were regulated by the FSMA Produce Safety Rule, while off-farm packinghouses were regulated by the Preventive Controls for Human Foods Rule. There is no science-based or risk-based rationale for regulating a packinghouse differently based on where raw agricultural commodities (RACs) are packed. Produce is not materially or compositionally changed or altered and does not undergo any substantial transformation at a packinghouse and thus should be solely regulated under the FSMA Produce Safety Rule and should not be predicated on where these activities take place. Nonetheless, this regulatory distinction still plagues FSMA implementation.

We applaud FDA’s efforts to clarify for produce businesses what activities constitute “harvesting,” “packing,” “holding,” and “manufacturing/processing” on farms and in food facilities. However, produce growers, handlers and others in the marketing chain must be able to easily understand when and what FSMA regulatory requirements apply to their business so that they can direct their attention to those activities that make products safer.

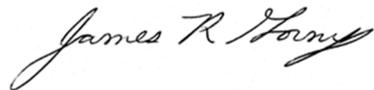
We recommend FDA acknowledge fresh produce is a unique food category and consider simply requiring foods that meet the definition of “produce” and “raw agricultural commodities” that do not undergo a “substantive transformation” during

postharvest handling be subject solely to coverage by the Produce Safety Rule, irrespective of where they are grown, harvested, sorted, packed or stored. A clear distinction between the coverage of these two rules would strengthen enforcement and reduce confusion in the produce industry and for regulators. It would also provide uniform and effective regulation of all postharvest activities, irrespective of physical location.

We fully understand that this simple yet effective solution will likely require congressional action to amend the Federal Food, Drug, and Cosmetic Act. We stand ready to work with FDA and Congress if needed, on a solution to these unintended consequences of the Food Safety Modernization Act.

The leading produce trade organizations have participated in the congressional debate about FSMA and provided comments to FDA at every opportunity in the development of final rules and now companion guidance documents. We greatly appreciate those earlier opportunities and the opportunity here to provide comments on this draft guidance to industry.

Respectfully,



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Appendix:

About Produce Marketing Association (PMA)

Produce Marketing Association is the leading trade association representing companies from every segment of the global produce and floral supply chain. PMA helps members grow by providing connections that expand business opportunities and increase sales and consumption. For more information, visit www.pma.com.

About United Fresh Produce Association

Founded in 1904, the United Fresh Produce Association brings together companies across every segment of the fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. We empower industry leaders to shape sound government policy. We deliver the resources and expertise companies need to succeed in managing complex business and technical issues. We provide the training and development individuals need to advance their careers in produce. Through these endeavors, we unite our industry with a common purpose – to build long-term value for our members and grow produce consumption.

About California Leafy Green Products Handler Marketing Agreement

The California Leafy Green Products Handler Marketing Agreement verifies, through government audit, that handlers and growers of lettuce, spinach and other leafy greens are following accepted food safety practices on the farm.

About the Canadian Produce Marketing Association (CPMA)

Based in Ottawa, Ontario, CPMA is a not-for-profit organization that represents a diverse membership made up of every segment of the produce industry supply chain and is responsible for 90% of the fresh fruit and vegetable sales in Canada. CPMA is fortunate to represent a sector that is both a significant economic driver for communities and that also improves the health and productivity of Canadians.

About Northwest Horticultural Council

The Northwest Horticultural Council represents the growers, packers, and shippers of apples, pears, and cherries in Idaho, Oregon, and Washington on federal and international policy issues.

About Western Growers

Founded in 1926, Western Growers represents local and regional family farmers growing fresh produce in Arizona, California and Colorado. Our members and their workers provide over half the nation's fresh fruits, vegetables and tree nuts, including nearly half of America's fresh organic produce. Some members also farm throughout the U.S. and in other countries, so people have year-round access to nutritious food. For generations, we have provided variety and healthy choices to consumers.

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