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Docket Management Branch (HFA-305)  
U.S. Food and Drug Administration  
12420 Parklawn Dr., Room 1-23  
Rockville, MD 20857

RE: Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability, Docket No. 97N-0451

To Whom it May Concern:

The following comments on the draft guidance are offered by the U.S. Apple Association (USApple), the national trade association serving the U.S. apple industry. USApple represents the United States' 9,000 apple growers and the industry's packer/shippers, processors and allied organizations.

Over one billion servings of fresh fruits and vegetables are consumed each day in the United States, yet illnesses associated with the consumption of fresh fruits and vegetables are extremely rare.

Of the 3,277 foodborne disease outbreaks reported between 1986-1996, less than 1 percent were linked to fresh produce. Of all traceable foodborne disease outbreaks, 97 percent resulted from improper handling and cross contamination at the point of preparation. These data suggest that the costly and burdensome regulation of agricultural production practices as suggested in the guidance document are unnecessary and improperly targeted at agricultural producers. In fact, USApple is unaware of any microbiological food safety illness to have occurred from the consumption of fresh apples. Therefore, the USApple believes that regulation of the production of apples is unnecessary to protect the public health and scientifically unwarranted.

Our industry is also extremely concerned with several points related to the fresh produce guidance:

- Our industry is concerned that the fresh produce guidance, which is now voluntary, will become mandatory through purchasing contracts or by future rulemaking.
- Many apple growers operate small orchards. These growers do not have sufficient time, money or management personnel to deal with complicated education and testing programs.

97N-0451

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- Approximately 23 percent of all fresh apples are exported. The apple industry is extremely concerned that foreign countries will use the guidance as a pretext to prevent U.S. imports, not for food safety reasons, but to protect their domestic apple industry from competition.

### **Specific Comments:**

#### **Preface (pages 1-2)**

As previously noted, the vast majority of food borne illnesses are caused by improper handling or cross contamination. Agricultural producers should not be held responsible for food handling practices of their customers.

#### **Introduction (pages 2-3)**

The agency notes that it has data suggesting that food borne illness resulting from the consumption of fresh fruits and vegetables is increasing. The draft guidance implies a link between this possible increase in foodborne illness and farming practices. Since this link is tenuous or non-existent in most examples used, it is imprudent to suggest that “marketability” may be affected unless growers and packers implement handling reforms.

#### **Use of this Guide (pages 3-4)**

Although development of the guidance document requires extensive knowledge of agricultural production practices, the Fresh Produce Subcommittee of the National Advisory Committee for Microbiological Criteria for Food included no members with a direct understanding of fresh fruit and vegetable production.

With regard to the sentence, “In many cases, current technologies cannot eliminate all potential food safety risks associated with fresh produce,” the phrase, “In many cases,” should be eliminated.

With regard to the sentence, “the guide does not specifically address other hazards to the food supply or environment (such as pesticides or chemical contaminants),” The gratuitous listing of “pesticides” as a hazard to the food supply should be dropped.

#### **Irrigation Water (pages 9-10)**

No one, including FDA, has the expertise to provide clear guidance on the water quality necessary for irrigation of orchards. Nor does FDA have the expertise to help growers judge the microbial disease risk of irrigation water coming in contact with any tree fruit crop. While growers are aware of commonsense risk factors, microbial ecology is complex and the “quality” of irrigation water based on microbial risk has little meaning beyond extreme instances. Suggestions implying that growers can improve water quality as harvest approaches

demonstrates a superficial understanding of irrigated agriculture and the limits of water source alternatives. The willingness to suggest potentially costly changes without a clear idea of why change is needed is a severe flaw in the proposed guidance document.

The agency does not have expertise in irrigation systems and does not have any basis to pose that drip irrigation is a preferred method of irrigation. USApple is not aware of any scientific studies that show that overhead irrigation is associated with food borne illness on apples.

Water testing has no rational basis since there is no standard for agricultural water quality and there are many limitations in testing irrigation water.

### **Processing Water (pages 10-11)**

Since USApple is unaware of even a single food borne illness associated with apples, there is no scientific basis for requiring water testing.

Daily cleaning and sanitizing of fruit handling equipment may be unnecessary and costly since most packing equipment has not been designed for such cleaning. Retrofitting of electrical and mechanical equipment would be costly to facilitate such cleaning and it has not been demonstrated to be necessary.

The agency's concerns regarding microbial infusion under specific produce-water temperature differentials as found in tomatoes should not be extrapolated to include other commodities without specific evidence that it causes a food safety problem. For some fruits and vegetables, removing field heat by applying cold water is essential to maintaining quality. The proposed guidance, which implies that there are significant risks over benefits from hydro-cooling, may be ill advised if not based on scientific data and a complete understanding of existing practices and needs. The agency should be cautious in suggesting that a food safety threat exists on the basis that a theoretical risk has been identified.

### **Sanitation and Hygiene (pages 18-21)**

Worker hygiene guidelines and training programs prescribed for food processing facilities will be difficult, if not impossible to implement. The agricultural work force, especially during harvest is transient and often employed on a short term basis. It would be extremely burdensome for producers to try to educate workers who might work for the producer for only a matter of weeks or even days. Agricultural producers must also be careful to avoid conflict with labor regulations that seek to minimize the influence that agricultural producers can exert over agricultural workers.

### **Pest Control (pages 25-26)**

The proposed guideline that suggests that "pests be eliminated" is impractical and impossible to obtain.