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2367 '98 JUL -1 A9:40

1712 '98 ~~JUN 31~~ July 1, A9:38

June 26, 1998

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

Docket #97N-0451

The Northwest Horticultural Council (NHC) hereby presents its comments on the April 13, 1998 draft guidance document, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, as prepared by the Center for Food Safety and Applied Nutrition of the U.S. Food and Drug Administration. The NHC represents the Idaho, Oregon and Washington tree fruit industry. Apples, pears, sweet cherries, peaches, nectarines, plums and apricots are the major crops produced by our over 5,000 growers and handled by our many packers and shippers.

**GENERAL COMMENTS:**

1. Our industry remains extremely concerned that the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (the Guide) will not remain a voluntary standard as now proclaimed by FDA. We believe the Guide will, at some point, become "mandatory" through 1) later rule making by FDA; 2) the operation of purchasing contracts imposed by large corporate buyers; or 3) through requirements mandated by liability insurance company policies. The NHC, therefore, takes the proposal very seriously and is quite concerned with its specific contents.
2. While it is common practice to consider fruits and vegetable as one class of agricultural products, the health risks that are the subject of the Guide are much different (and less) for tree fruit crops than certain vegetables.
3. Apples, pears and sweet cherries have been grown commercially in America since it was colonized. The federal government should be extremely cautious in expanding its reach into an industry that has grown its products successfully and safely for centuries.
4. Any proposed standards for production must take into account that most orchards are family owned and less than 50 acres in size. These growers do not have the time, money or management to oversee complicated education or testing programs.

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5. Our government must recognize that any standard imposed or suggested for U.S. agriculture may have great impacts on the foreign trade of fresh fruits and vegetables. Other countries can seize upon such standards as means to prevent or hinder imports – not to improve food safety but to protect their domestic agriculture from competition.
6. Fruits and vegetables, whether grown in a backyard garden or in a commercial field, are open to the elements. Their production is inherently bound up with getting one’s hands dirty. Wild animals come and go. Equipment, whether a shovel or a tractor, engages with the soil and does not remain as clean as when purchased. Guidance that does not recognize this overall practical reality will be viewed by growers, those who provide the world with food, as useless edicts from the federal city.
7. While we make a number of specific comments, as presented below, we have chosen not to discuss each section of the draft guidance document. This does not constitute an endorsement of those sections that have been left uncommented upon. We expect other knowledgeable parties to point out possible faults or suggest improvements in areas where we lack specific expertise.

#### **SPECIFIC COMMENTS:**

##### **Preface (page 1-2 of 37)**

- It is unrealistic to expect growers to assume responsibility for the food handling practices of their customers, most of who are many steps removed from the farm and packinghouse. Most growers in our industry own family orchards and are not economically in any position to take on food safety education tasks better suited to larger organizations such as retail supermarkets, large restaurant chains and national agencies of government.

##### **Introduction (page 2-3 of 37)**

- 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 food borne 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 (page 3-4 of 37)**

- Based on our understanding of FDA’s internal process of developing the guidance document, we understand that there were very few experts involved with a working understanding of agricultural production practices. The Fresh Produce Subcommittee of National Advisory Committee for Microbiological Criteria for Food included no members with a direct understanding of fresh fruit and vegetable production.
- “In many cases, current technologies cannot eliminate all potential food safety risks associated with fresh produce.” The phrase “In many cases” should be dropped.

- “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 (page 9-10 of 37)**

- 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 common sense risk factors, microbial ecology is complex and the “quality” of irrigation water based on microbial risk really has little meaning beyond extreme instances. Further, to suggest that a different source of irrigation water should be used or that this undefined standard of “water quality” should improve as harvest approaches demonstrates a superficial understanding of irrigated agriculture and the limits of water source alternatives in the arid West. 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.
- Since the agency is also without expertise in irrigation system design and evaluation, it should drop references to the supposed benefits of drip irrigation. There are many other types of irrigation delivery systems that also do not wet the edible parts of the plant depending on the crop being grown. Additionally, since there is no documentation supplied which links overhead irrigation to food borne diseases, using overcrop sprinkling as an example of a potentially bad practice is unwarranted.
- Since there is no standard for agricultural water quality beyond the obvious and commonsense, water testing has no target or rationale.

### **Processing Water (pages 10-11 of 37)**

- Since outbreaks of microbial food borne illnesses have not been linked to commercial tree fruit produced by growers in the Northwest, we do not see a clear mandate or adequate information regarding the general need for water testing for potentially harmful human pathogens. Again, without a specific understanding of testing targets, sampling would be costly and could be futile.
- Daily cleaning and sanitizing of fruit handling equipment may be unnecessary if a particular piece of equipment has been used sparingly and/or maintained properly.
- The concerns regarding microbial infusion of tomatoes under specific produce-water temperature differentials should not be cavalierly expanded to a broad spectrum of commodities as is implied in the guide without specific evidence. For some fruits and vegetables, removing field heat by applying cold water is essential to maintaining quality. Guidance which implies that there are significant risks over benefits from hydro-cooling may be ill advised if not based on hard scientific data and an understanding of existing practices and needs.

**Sanitation and Hygiene (pages 18-21 of 37)**

- Worker hygiene guidelines and training programs prescribed for food processing facilities will be difficult, if not impossible, to implement especially in harvests of highly perishable commodities that often demand huge increases in a farmer's work force. In many situations, these harvesters are employed for a very short period of time, sometimes merely days. Under these conditions, and without better evidence of actual problems, rigid and extensive standards for thorough personal hygiene training and surveillance for infectious diseases are highly unlikely to be accepted and successful in the real world of farming.

**Pest Control (pages 25-26 of 37)**

"Ensure that all potential nesting or hiding places for pests have been eliminated". This direction is patently unobtainable.

**Trace back (pages 28-30 of 37)**

- Our industry has trace back systems in place for cartons of fruit. However, once fresh fruit leaves the wholesale container, it loses its identity. Expecting growers and shippers to institute and pay for systems that will ensure absolute trace back for each individual piece of fruit to the grower is impractical and would cause an unreasonable financial burden. Further, surely FDA does not expect growers and shippers to document the entire chain of product handlers once produce has been sold?

(End of Comments)

Submitted by:

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Northwest Horticultural Council



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WCSL 0497  
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