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97N-0451

June 24, 1998

Dockets Management Branch (HFA-300) 638 '96  
U.S. Food and Drug Administration  
12420 Parklawn Dr., Room 1-23  
Rockville, MD 20857

Docket # 97N-0451

Dear Sir or Madam:

Thank you for the opportunity to comment on the April 13, 1998 draft guidance document, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. The comments of the United Fresh Fruit and Vegetable Association (United) reflect the perspective of our broad membership and our desire to assure continued consumer confidence in all produce commodities.

United is the national trade organization representing the interests of producers and distributors of commercial quantities of fresh fruits and vegetables. United represents the business interests of growers, shippers, processors, brokers, wholesalers and distributors of produce, working together with our customers at retail and foodservice, our suppliers at every step in the distribution chain, and our international partners.

United members appreciate the Food and Drug Administration's (FDA) effort to provide industry with multiple opportunities to comment on draft guidance during the process of developing final guidance. Since the launch of the President's produce initiative, we believe FDA has gained valuable insight into the operation and complexity of the produce industry. United is quick to recognize that the April 13, 1998 draft guidance document (hereinafter referred to as draft guidance) is much changed from the preceding, more highly flawed, November 1997 working draft guidance document.

Most important, United believes the draft guidance properly captures the spirit and tone of what guidance should be: an agency document that focuses industry attention on key areas of potential risk and prompts the implementation of effective, voluntary measures to minimize or prevent the occurrence of microbiological hazards.

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United Fresh Fruit & Vegetable Association

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While the draft guidance is much improved over the preceding draft, United has a few specific comments regarding the content of this document:

- o In the discussion of microbial hazards possibly associated with water, section II.A., the draft guidance refers to a 1995 outbreak of *E. Coli* O157:H7 involving at least 29 people. The use of this reference is entirely unnecessary and undermines the credibility of the draft guidance. The draft guidance states, "While it is not known where the lettuce became contaminated, investigators noted that the lettuce was irrigated with surface water . . . ." United suggests that the discussion of microbial hazards associated with water is strong enough without the need to refer to an outbreak where the connection to irrigated water is tenuous at best.
- o The draft guidance includes a reference, in section II.B., 2.0, to Good Manufacturing Practices as set in Title 21 CFR 110 and later a reference is made to FDA's Food Code. We suggest that where possible, the guidance should reprint the most salient points from these or any other similar references. The intended audience for the draft guidance may not have ready access to the Code of Federal Regulations. If reprinting the most important sections of these references would be too lengthy, then we suggest that a section be added that describes to the reader how copies of these reference materials can be obtained.
- o The discussion of microbial hazards in section IV. Sanitation and Hygiene could benefit from greater elaboration. Many examples exist where poor hygiene and sanitation practices by food handlers have resulted in outbreaks of foodborne disease. The use of clear examples would help provide the reader a better understanding of the importance of maintaining proper hygiene and sanitation to the prevention of outbreaks.
- o In the Footnotes section at the end of the guidance document, reference is made in Footnote 2 to USDA's Agricultural Marketing Service's "Qualified Through Verification" program for fresh-cut produce. United has previously commented extensively to USDA that this pilot program still in development has never been presented to the industry or public for review and comment, and that at present, significant deficiencies exist in its scientific basis and application in the industry. USDA has indicated that it intends to publish a review of the program and seek public comment in the near future. Therefore, we believe it is highly premature for FDA to refer industry operators to a program that is in pilot development and has yet to resolve questions as to its scientific and technical merits.

Beyond these specific recommendations, we want to offer several more general comments.

First, we commend FDA's decision to allow adequate time for developing and finalizing produce guidance. At the outset of the President's initiative, United was very concerned that the planned timeline for developing guidance was far too rapid and would have resulted in the development of unacceptable and ineffective recommendations. We hope FDA will view the final guidance as a work in progress. Any future amendments to final guidance should be based upon sound science and valid conclusions regarding the effectiveness of any proposed intervention measures.

It is evident upon reading the guidance that much remains to be learned regarding the possible origins of microbiological hazards that may be associated with produce, much less the most effective intervention measures. While this document does a creditable job of focusing attention on risk minimization steps at the growing and packing level, FDA must accept that the majority of foodborne illness associated with produce consumption occurs through contamination farther along the distribution and marketing chain. The evidence is strong that future efforts to minimize microbiological risks should focus on proper handling of fresh fruits and vegetables in central food preparation facilities, retail establishments, and in the home.

To this point, United finds a mindset among some public health officials that outbreaks associated with a specific eating occasion must immediately be linked to the production of the specific commodity involved. However, past analysis of foodborne disease outbreaks clearly indicates that the majority of cases are related to cross-contamination subsequent to production. American consumers will be ill-served by a mindset that treats fresh produce similarly to a manufactured product, with the false expectation that contamination most often occurs at the production level.

We believe that FDA's enhanced investigation, study and monitoring of produce industry practices in recent years would confirm that there are no systemic problems associated with the production and handling of produce that result in routine contamination of produce, leading to ongoing, frequent outbreaks of illness.

As a result, when produce is implicated as a vehicle for foodborne disease, the cause is most likely to be cross-contamination close to the eating occasion, or otherwise an anomalous event at production level. Therefore, we urge FDA to continue its work with the Centers for Disease Control and Prevention, state and local public health officials, USDA and the industry on scientific evaluation of foodborne disease outbreaks. The lessons FDA has learned in studying the produce industry to prepare this guidance document should be communicated to all of those public health partners who may unwittingly make false assumptions about potential points of contamination without sufficient knowledge of the safety precautions present in the industry.

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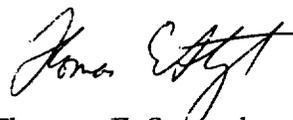
We also urge FDA to support research through direct funding and to maintain an ongoing dialogue with USDA and the industry on new technologies and practices from *farm-to-table* that may help prevent and/or reduce risks further.

United believes the produce industry grows, packs and distributes a remarkably safe and abundant supply of fresh fruits and vegetables that are critical to the health of our country's consumers. With over a billion servings of fruits and vegetables consumed each day in the United States, we truly have a remarkable safety record in producing and marketing these products. Fresh fruits and vegetables offer consumers wonderfully healthy products, and concerns about sporadic cases of foodborne disease must not force consumers or the industry into a counterproductive response that would diminish the health benefits of these products.

The fresh produce industry has made significant advances in recent years in understanding and responding to microbiological food safety issues. Industry operators today routinely indicate that microbiological food safety issues are a top priority and numerous trade associations representing specific commodities, growing regions or sectors of the industry have developed educational materials and programs to assist growers and handlers of produce in minimizing the possible microbiological risks. We strongly encourage FDA to work closely with industry trade associations in continuing to develop common answers to food safety questions.

The draft guidance, once finalized, will be a valuable tool for promoting a common understanding of potential microbiological hazards associated with the production and handling of produce. However, United must make clear that the most effective means for disseminating this guidance to the industry will be through a concerted outreach and education program led by the U.S. Department of Agriculture in cooperation with the industry itself. We want to emphasize that any attempt to translate guidance into a rigid regulatory tool will fail.

Sincerely,



Thomas E. Stenzel  
President and CEO