



Florida Department of Agriculture & Consumer Services
BOB CRAWFORD, Commissioner
The Capitol • Tallahassee, FL 32399-0800

June 26, 1998

Please Respond to:

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

1063 '96 JUN 30 A9:34

RE: Docket No. 97N-0451

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability

It is imperative that agricultural production in the U.S. be retained and encouraged. It is further imperative that we minimize microbial food safety hazards in the fresh fruits and vegetables that we produce. The end result of our good intentions in this draft document must not lead to driving this country's agricultural production off-shore where little to no controls exist in environments that have contaminants unknown in this country and where the Center for Disease Control and Prevention provides traveler warnings concerning consumption of raw agricultural produce and water from those environments. Current import regulation which involves end product inspection of less than 2% of the imported products is insufficient when compared with current agriculture growing practices. Additionally, HACCP, while an important improvement, has proved insufficient for these off-shore environments as evidenced by the previous Cyclospora outbreaks in this country and the current outbreaks in Canada. The recent GAO Report, FOOD SAFETY: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable, clearly and definitively reports the inadequacy of this segment of our food safety system. North Americans are being exposed and will continue to be exposed to contaminants against which they have no immunity from some off-shore environments. Therefore, it is imperative that agricultural production in the U.S. must be retained and encouraged.

The states of California and Florida are synonymous with fresh fruits and vegetables. Medical authorities from all sources praise the contributions of fruits and vegetables to our diets as critical sources of nutrients and for their cancer and chronic disease prevention attributes. Yet, in this very arena, we continue to monitor the escalation of imports of fresh fruits and vegetables from many nations who do not maintain the same sanitation of water sources and worker standards that we require in the U.S.

We appreciate the FDA seeking input from the states and from the fruit and vegetable industry in developing this draft document in such a short period of time. FDA has appropriately attempted to identify the elements of risk associated with fresh fruits and vegetables and how

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they must be reviewed for their impact on food safety, must be clearly understood and must be adequately monitored and controlled by the producer. However, the document does not clearly demand a verification that our trading partners are adhering to the same strict standards that we have in place at the present or in the future when the draft guidance becomes a reality.

While I support the document's goal to minimize microbial food safety hazards from fresh fruits and vegetables, I deplore the fact that our nation has been unwilling to apply our current standards of sanitation to our competitors in the marketplace. Will our U.S. standards of food safety be enhanced if we reduce the numbers of our U.S. growers with unequal requirements? I strongly doubt it. No matter what document is accepted, we must actively impose the guidance both domestically and abroad to ensure equivalent food safety protection for all.

Agricultural producers can ill afford occurrences of food borne illness outbreaks associated with fresh fruits and vegetables. The perishability of fresh produce makes it mandatory that moves produce through the market uninterrupted. Anything that delays this process can cause major economic loss to the producer. Producers certainly want to avoid making people sick and are, therefore, very anxious to learn and adopt new agricultural practices to minimize or to eliminate risks. While it is impossible to grow crops in a sterile, bacteria free environment, it is prudent to limit the occurrence of microbial contamination and, more importantly, to control any opportunity to prevent the spread and/or multiplication of microbial contamination.

Many of the recent outbreaks are the result of uncontrolled packing/processing environments, the preparation of value-added products in which cross contamination occurred, environmental poor judgements allowing contamination of product, and contaminated imported products.

Because sporadic microbial contamination is a reality regardless of agriculture practices in the field, guidance at the producer level must not be even remotely viewed as adding liability or *de facto* regulations on the growing operation. I believe the document should reflect its role as an educational tool rather than be a definitive guide on "best" practices. "Best" practices are unique to each growing area, its environmental demands, the weather, the crop and its intended end use, and numerous other uncontrollable variables.

Agricultural production is so diverse it is difficult to write a general guidance document to fit all possible crops and possible end products. Opportunities for microbial contamination in the open, natural environment are plentiful, from fowl to wildlife and domestic animals. The draft document does not adequately establish a clear, delineations between controls that are

expected and readily achievable in an enclosed food processing area and those controls that are practical and achievable in the open environment. I encourage the Agency to work closely with the produce industry and the various trade associations to precisely differentiate between the realistic expectations in these two arenas. Clearly, domestic animals should be precluded from growing areas, but it is impossible to eliminate birds and wildlife and subsequent sporadic contamination. Technologies must be advanced to handle the realistic sporadic contamination that can and does occur. Control of sporadic contamination, while important, does not need to be the major emphasis. Intervention strategies must be implemented at the point where they are most efficient and cost-effective. The control strategy should be implemented at the producer level only as a last resort since this is the critical point in the continuum where the cost of the control can not be passed on to the end user, the consumer.

The guidelines for improvement of our agriculture industry at the producer level must maintain a sense of balance, be reasonable and not overly burdensome, be cost-effective, be science-based, and deliver a measured increase in food safety. It is very important that a global approach to the role of fresh fruits and vegetables in disease prevention not be overlooked and that the cost of production not force the price of food higher, thereby limiting access, nor force production off shore to lower production cost environments that may pose even more significant public health issues.

I believe education is what the agriculture production community needs and not *de facto* regulations. The agriculture production community moved into the value-added, ready-to-eat raw agriculture products, in some instances, without the necessary transition into a rigorously controlled food processing environment. This resulted from demographic food consumption changes and a need to maintain a profit at the production level. Farming in this country was losing its profit margin and its competitive edge in the global marketplace in part due to an ever-increasing imposition of environmental and pesticide management practices which are not equally shared by off-shore operations. Much of the produce industry lacked the knowledge in microbial food safety to realize the risk associated with this transition and, consequently, the entire industry bears the burdens of these failures.

The Food Safety Program in my Department began examining the microbiological quality of raw ready-to-eat produce in early 1990's and cited numerous firms for significant levels of *E. coli* in their processed products. By 1995, the microbial quality of these products had markedly improved. I know of no other regulatory program examining these issues at that time, much less taking action. Generally, the cooperative extension and the regulatory community education efforts failed to be proactively involved in the transition to value-added, ready-to-eat raw produce which would have provided a stronger knowledge base to ensure food safety.

It is our opinion that if one chooses to produce a ready-to-eat, value-added, raw agriculture product, one must choose to do so in a rigorously controlled food processing environment that is designed to remove expected sporadic contamination and prevent any microbial multiplication of naturally occurring pathogens. Many of the outbreaks from these products, including fresh juices, were from food establishment environments that had little or no compliance with good manufacturing practices. While the original contamination may have occurred in the field as a sporadic incidence, the food establishment insanitation and processing conditions provided the necessary environment for cross contamination and microbial multiplication.

With regard to specific language in the draft document, my staff offers the following comments:

- 1) Introduction section, last paragraph, last sentence: Add the following words after the word produce, "that is intended for consumption without further processing."
- 2) Section II Water, paragraph 1 Add "to be eaten raw" after "produce" in the last sentence.
- 3) Section II Water B (Control of Potential Hazards) paragraph 1, 4th sentence:
Examples of produce with a large surface area and those with topographical features that foster pathogen attachment should be given in order that readers understand more thoroughly what you are defining, i.e., lettuce and cabbage for a large surface area and raspberries and other berries for the second example.
- 4) Section II Water B, Section 1.0 Agriculture Water, paragraph 1: Water with raw sewage or untreated manures must be prohibited from use in irrigation. treating irrigation water to reduce microbial loads is not a viable cost-effective solution. Potable water must be required for end packing and processing as appropriate to the specific crop.
- 5) Section II Water B, Section 1.1 General Considerations, Bullet #2 Human sewage contamination is less frequent in this country than in developing countries. Most waste is treated and there are environmental rules that minimize contamination from raw sewage. Also, this section fails to take into account that rainwater may contaminate crops by splashing contaminated dirt onto the fruit and vegetable surfaces.

- 6) Section II Water B, Section 1.2 (Irrigation water), 2nd paragraph (Be aware of risk factors), last sentence: Add the following words after the word harvest, "And if no further processing is anticipated."
- 7) Section II Water B, 2.0 Processing Water, paragraph 2 This paragraph needs emphasizing since it represents the major cause of recent outbreaks. Processing ready-to-eat products requires a rigorously controlled food processing environment.
- 8) Section II Water B, 2.0 (Processing water), Section 2.2 (Wash water). What is the difference between processing water and wash water? Is it the step at which the water is used; i.e., initial wash water vs final processing water? There should be some differentiation made between the two waters if there is really a difference.
- 9) Section II Water B, The boxed statement at the end of 2.1: "While prevention of contamination is preferred over application of chemical sanitizers after contamination occurs" is somewhat bureaucratic in that all raw produce has to be assumed to be sporadically contaminated with pathogens. Our natural environment where agricultural produce is grown is not sterile.
- 10) Section II Water B, 2.2 Wash Water, Bullet 1, sub-bullet 2; Insert after washing, "if appropriate for the crop". Delicate produce may be damaged by vigorous washing which would increase the retention of surface pathogens.
- 11) Section II Water B, 2.2 Wash Water, Bullet #3 Last sentence should be qualified as applicable to produce to be eaten raw.
- 12) Section II Water B, 2.2 Wash Water, last paragraph: Add "The alternatives under study are best utilized in a controlled environment, i.e., processing room.
- 13) Section IV (Sanitation and Hygiene), paragraph 2.1, paragraph 2, 4th sentence: A formalized training program is not very practical for the type of workers that we are trying to train. Turnover is great. Formalized training in a field environment is less than realistic.
- 14) Section IV, paragraph 2.1, Personal Health and Hygiene Bullet # 3, 1st sentence: Change word diagnosed to "showing symptoms". Also change excused to "excluded".

- 15) Section IV, paragraph 2.1, Bullet # 3, last sentence: Add the following to the last sentence after the word, produce, "or any food or food equipment/utensils.
- 16) Section IV, Section E (Customer Pick Operation ...) If operators are to educate consumers, then educational material should be furnished to the operators.
- 17) Section IV, Section F (Transportation), 1st paragraph, line 1: Replace word, product, with "produce".
- 18) Section IV, Section F, Paragraph 2.1, 2nd bullet": Replace word, product, with "Produce".
- 19) Section V, Boxed statement in Trace back, 2nd line: Replace word, management, with word, "agriculture".
- 20) Section V (Trace back), paragraph 1, 3rd sentence: Replace word, management, with word, "agricultural".
- 21) Section V on trace back has no mention of repack operations. Repacking operations are key points that must be addressed because of the issues of co-mingling, trace back, origin and cross contamination. A large percentage of certain commodities go through routine repacking before reaching the ultimate consumer.
- 22) Section V, last paragraph, last sentence: Change word, technologies, to "procedures". Examples given are not technologies, but rather trace back procedures.

Thank you for the opportunity to comment on this important issue. This draft guidance document is a very significant evolution in developing farm - to-table strategies to reduce the risk of foodborne illness. We must continually look for cost-effective ways to improve the safety of raw, ready-to-eat agricultural fruits and vegetables which are so vital to a healthy, disease prevention diet.

Sincerely,



BOB CRAWFORD
COMMISSIONER OF AGRICULTURE

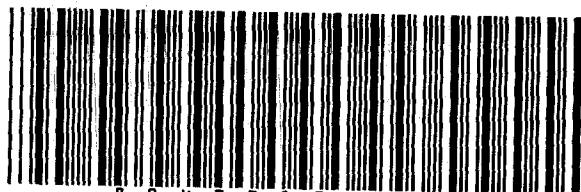
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