



United Fresh Fruit
& Vegetable Association

December 19, 1997

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

Re: Docket No. 97N-0451: Microbial Safety of Produce: Grassroots and International Meetings

We appreciate the opportunity to comment on the President's initiative to ensure the safety of imported and domestic fruits and vegetables and other foods, announced October, 2, and specifically on FDA's "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (hereinafter referred to as "the guide"). We support the intent of the initiative and recognize that foodborne disease is a serious national health issue. The United Fresh Fruit and Vegetable Association supports action to reduce the incidence of foodborne illness and is not opposed to federal guidance if it is developed at an appropriate pace, using a methodical, science based approach, in concert with a broad spectrum of industry experts. We look forward to working cooperatively with FDA and USDA to bring the President's initiative to a successful reality.

The following points summarize United's key concerns with the President's initiative and FDA's "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables:"

GENERAL COMMENTS

1. *Guidance is preferred over regulation because it affords the industry and the Agencies flexibility.* Given the lack of concrete information upon which to base recommendations and the complexity and diversity of the industry, guidance is an appropriate, effective response. Also, guidance, not regulation, will have the flexibility to accommodate the necessary science, as it becomes available.

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2. *While this is guidance, buyers of fresh produce will use it as a standard on which to base their purchasing agreements, making it de-facto regulation.* We urge FDA to recognize this in moving forward and insure that sufficient language is included to minimize misinterpretation of any recommendations. After all, there may be many reasons to depart from this guidance, given the industry complexity.
3. *The current pace threatens to jeopardize produce industry participation and ignores the complexity of our industry.* The industry urges FDA and USDA to convey to the Administration that more time is necessary to produce guidance that portrays what is practical, reasonable and based in sound science.
4. *Any guidance developed by the U.S. Food and Drug Administration and U.S. Department of Agriculture for the produce industry, must be based on sound science and reasonable information.* Federal guidance cannot impose prescriptive, arbitrary, recommendations. Instead, the agency must limit the scope of guidance and policy to what is known. To the extent that any recommendations are grounded in sound science the industry will support them.

The industry welcomes education about any risks associated with agricultural and handling practices, and is quick to adjust when science warrants. However, industry operators should not be unjustly burdened because scientific information lags behind epidemiological evidence, forcing compliance with ungrounded recommendations.

5. *Commodity specific guidance is unnecessary. Broad industry guidance is sufficient to prevent food safety problems.* Instead of focusing government resources on developing commodity-specific guidance we recommend that industry and government work in partnership, through a Memorandum of Understanding, to develop education and outreach programs based on broad FDA guidance. It is under this cooperative framework that we, together, can make a true impact on public health. After all, results, not words, will give consumers confidence.
6. *Good Agricultural Practices and Good Manufacturing Practices are appropriate for assuring the safety of whole commodities, NOT Hazard Analysis and Critical Control Point programs.* HACCP is a food safety system grounded in science. Because the scientific understanding of what gives rise to contamination of produce is very limited, HACCP is an inappropriate regulatory response.

7. *Additional meetings throughout the industry, including field tours, are essential before completing the development of broad industry guidance.* The current haste with which the initiative is moving forward prohibits those drafting guidance from gaining an adequate understanding of current industry practices and regulations, jeopardizing any federal guidance effort. Additional meetings are necessary in California, Texas, and other states to accommodate industry feedback. Field tours are also an essential part of understanding industry challenges and complexities. We urge the Agencies to capitalize on our offer to coordinate tours to facilitate gaining a firsthand view of our industry.
8. *Guidance must refer to any state, regional, and local regulations currently in place.* Industry representatives at every grassroots meeting conveyed that water use, manure and biosolids use, and wild life are governed by another agency's regulations. Water use is restricted in every region, including what water source an industry operator can use, how much, and when. Federal EPA's Part 503 Rule promotes the use of biosolids for "maintaining or improving environmental quality and protecting public health." Wildlife management agencies in every region have strict provisions that make it impossible to restrict wildlife movement.
9. *Measures to permit rapid approvals for new technologies and new uses of existing technologies should be identified and implemented.* FDA, USDA, and EPA should review their approval processes for new technologies and new uses of existing technologies that address public health concerns associated with fresh produce.
10. *As the initiative moves forward to contemplate means to affect standards in countries importing to the U.S. market, it must do so in a manner consistent with free trade principles.* Forcing our trading partners to follow a document not based on science will inevitably be challenged as a non-tariff trade barrier.
11. *Through this and other components of the initiative it is imperative that the Agencies and the Administration clearly state the importance of increasing consumption of fresh fruits and vegetables.* At a time when incidence of chronic diseases such as cancer, heart disease, and high blood pressure, are on the rise and when an overwhelming number of scientific studies indicate that consumption of fresh fruits and vegetables (5 to 10 svgs/day) can decrease one's risk of many of these diseases, we must not jeopardize the public's health by inappropriately steering them away from fresh fruits and vegetables. Instead we must continue to support national initiatives that encourage increased consumption of fresh fruits and vegetables.

SPECIFIC COMMENTS

Our comments that follow are specific to FDA's Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables.

Preface

Page 3:

We recommend the term "good handling practices" be used in place of "good manufacturing practices" throughout the guide and initiative. Good manufacturing practices (GMPs) are codified regulations, whereas the guide is intended to be guidance. Using a term that is widely known as regulation in the context of federal guidance for fresh fruit and vegetable production is likely to be misinterpreted and confusing to regulatory officials, industry operators, and buyers.

Page 3:

Development of guidance for specific commodities is unnecessary. Instead of focusing government resources on developing commodity-specific guidance, we recommend that industry and government work in partnership, through a Memorandum of Understanding, to develop education and outreach programs based on broad FDA guidance. It is under this cooperative framework that we, together, can make a true impact on public health. After all, results, not words, will give consumers confidence.

Introduction

Page 5:

We suggest the statement "although the reported incidence of foodborne infection from fresh produce is relatively low, it is increasing" be restated as "although the reported incidence of foodborne infection from fresh produce is relatively low, fresh produce has been increasingly found to be a vehicle of foodborne illness."

Clarifying that fresh produce is the *vehicle* of foodborne illness more accurately portrays the epidemiological information, and will minimize misinterpretation.

Page 6:

We recommend that the term "municipal biosolids" be used rather than "municipal sewage sludge." Municipal biosolids is a more contemporary term and more accurately portrays that it is the by - product of human waste digestion, not human waste, that is used for fertilizing.

II. Water

Section A. Microbial Hazard, Page 8:

The epidemiological investigation of this *Salmonella* outbreak determined that GMP's were not being followed by the orange juice processor. Tree frogs, whose fecal matter contained *Salmonella*, were determined to be the likely cause of contamination. In fact, the surface water was not characterized as the source of contamination (1).

Section B. Control of Potential Hazards, Page 9:

Suggesting that "water quality may need to be greater for overhead spray irrigation than for drip irrigation" does not take into account the multiple and sometimes unforeseen forces that dictate irrigation methods.

We recommend replacing the above statement with "be aware that the potential for and extent of produce contamination by pathogens may be influenced by the source and method of irrigation employed. To prevent contamination, water used for irrigation should be of appropriate quality. To achieve the greatest potential impact on public health, efforts should be focused at the potential sources of contamination, not solely on interventions.

Section 1.0 Agricultural Water, Page 10:

Testing water sources to determine if they are "safe for intended use" is an insufficient safety management system due to the low probability of detection. Instead, testing should only be recommended to evaluate an intervention's effectiveness. For example, if water is chlorinated, testing to insure chlorine levels and pH are maintained appropriately may be warranted. However, testing municipal water sources to assure "sufficient quality" should not be a requirement and burden placed on individual operators.

The responsibility of assuring the quality of water, when using a public source, should not be that of individual operators. Because a number of factors could contribute to water source contamination, it is unreasonable for individual operators to have complete responsibility for testing and intervening, if necessary, to assure that water used for irrigation is "safe for the intended use." For example, if one operator found that river water was not of "sufficient quality," he would be obligated to intervene, as would all growers using the same source. Instead, the focus needs to be on addressing the source of contamination, such as contaminated effluent from an upstream sewage treatment plant, or feedlot runoff. This obligation should reside with the local, county, or state water district having jurisdiction, not the individual grower.

Section 1.0 Agricultural Water, Page 11:

We suggest omitting the statement "alternative application methods that reduce or avoid water-to-produce contact" as a control mechanism to ensure that water quality is sufficient for its intended use.

Growers do not have access to multiple water supplies. At every grassroots meeting the industry conveyed the explicit regulations governing water use, often including what water source an industry operator can use, how much, and when.

We suggest omitting the statement "delaying water use until quality improves" to ensure that water quality is sufficient for its intended use.

There is no room to maneuver when a crop needs water. While the guidance recognizes that the "feasibility of these, or other, controls will depend on the intended water use and the needs and resources of a particular operation," the recommendations are impractical. Rather than suggesting impractical and unproven intervention strategies, the quality of irrigation water should be assured by the overseeing water district. Advice absent of a public health impact will result in stretching resources without any additional assurance of food safety.

Section 2.1 Wash Water, Page 15:

The referenced research on tomatoes indicates that "*Salmonella* in a water bath may be rapidly internalized by tomatoes when the water bath temperature is colder than the tomatoes." Based on this study FDA guidance recommends that "wash water for tomatoes be hyperchlorinated and 10° F warmer than the tomatoes." We have two concerns with this recommendation:

- Promoting hyperchlorination to enhance food safety could have far reaching environmental implications that need to be considered.
- Maintaining water at a temperature greater than produce prevents what is often a grower's primary goal -- to remove field heat from the product.

Brian Haddix, of the California Grape and Tree Fruit League, stated at the Oregon grassroots meeting on December 12, that fruit picked in the summertime is often 105° F or greater requiring a 115° F wash bath temperature. This would not enable removal of field heat which preserves both the quality and safety of the produce.

We recommend that the statement read "this research shows the importance of maintaining water used in washing operations free from pathogens, so that no matter what temperature differential exists between the product and wash water, produce contamination is prevented."

III. Manure and Municipal Sewage Sludge

Section 2.2.1 Untreated Manure, Page 19:

Specific application - to - harvest delay minimums for untreated and treated manure should not be set in the absence of sound science. Without this base any recommendations will not impact public health.

The guide refers to two scientific studies, one that was conducted in a test tube and another that has not yet been published. While both are important to the advancement of our understanding of pathogen survival in animal manure and signal the need for more research, neither is sufficient to base policy upon.

The industry agrees with the recommendation to "reduce the risk of contamination from manure by maximizing the time between application of manure to a field and harvest." However, we do not support referencing standards or practices that merely *exist* today but were not based on microbiological food safety concerns. For example, the statement that "intervals of ... 120 to 150 days between application and harvest of manure for stone fruit" was included based on a rhetorical question asked during the November 19, National Advisory Committee on Microbiological Criteria for Foods (NACMCF) meeting. We urge you to apply greater discrimination when developing recommendations and assure that they flow from scientific findings, not casual comment.

While it may seem that the industry opposes all recommendations as a means of minimizing burdensome regulation on the industry, that is not the case. We believe that through educated hypotheses and common sense there exists a starting point upon which to evolve as science becomes available. However, this information is not strong enough to base policy on. Rather, the short-term focus should be on education using a common sense approach and based on broad FDA guidance.

The suggestion to plan "crop rotations where manure is applied to fields planted with crops that are to be cooked or properly heat processed prior to being delivered to consumers" does not have broad industry application. It does not account for commodities in which multiple crops are grown each season nor for other forces that may prohibit this type of crop rotation.

Section 3.0 Animal Feces, Page 21:

High concentrations of wildlife are undesirable to the industry as well as public health officials because they consume produce and because their feces may carry pathogens that could potentially contaminate product. However, at the grassroots meetings it became clear that wildlife management agencies often times prohibit growers from intervening. For example, the Department of Natural Resources in New York State manages the deer population and will not allow public intervention. In Florida one grower was prohibited from trying to remove a bear and her cubs from his orchard by the overseeing wildlife management agency.

It must be recognized that other agency's recommendations could be in direct conflict with this guidance and must be considered.

IV. Sanitation and Hygiene

Section 2.1 Personal Health, Page 22:

The guidance states "it is suggested that operators train employees to report to the person in charge any information about their health or activities as they relate to diseases that are transmissible through food" and that "workers should be taught to report symptoms caused by illness, infection, or other source that is associated with..." While the intentions are sound and make sense, it is unlikely to work both from an industry operator and farm worker perspective.

Throughout the grassroots meetings this was posed as a significant issue by extension agents, industry operators, and the United Farm Workers because:

- The industry must respect the privacy of their workers.
- Workers are afraid to convey health information for fear of being fired or retaliated against.
- Workers cannot afford to miss a day of work, prohibiting them from declaring any illness.

Section 2.3 Harvesting Precautions, Page 26:

At the November 19, NACMCF meeting CDC and other public health officials clearly stated that do not advocate glove use as a substitute for maintaining clean hands. Since, references in the guidance that employees use gloves have been omitted. However, we believe that glove use should not be recommended for anyone handling produce, including inspectors and buyers. Instead, handwashing should be recommended for all persons. Promoting one message, without exception, whether a federal recommendation or industry management decision, will result in greater compliance.

Section D. Transportation, Page 30:

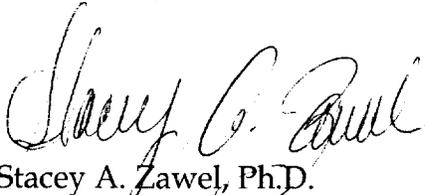
The draft guidance states that the U.S. Code of Federal Regulations requires that "storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination." While the produce industry agrees with this and recognizes their role in assuring that transportation vehicles are in the appropriate sanitation condition prior to loading, industry operators do not have control over the transportation link once it leaves their dock. Therefore, it is essential that the President's food safety initiative include focus on the transportation segment of the distribution chain in order to assure a seamless food safety system.

V. Positive Lot Identification

Page 31:

It may seem simple to request that growers include tracking information on their packages, but without efforts by everyone in the distribution chain to maintain the product's identify no benefit will be achieved. Therefore we recommend that this challenge be approached differently. We encourage the Agencies to take advantage of the work that the industry, along with it's distribution partners, has already begun. *If the inclination still exists to develop federal recommendations then we encourage the agencies to provide the leadership to work in partnership with all segments of the production and distribution chain to effectively address this challenge.*

Respectfully submitted,



Stacey A. Zawel, Ph.D.
Director, Scientific and Regulatory Affairs

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