



January 26, 1998

United Fresh Fruit
& Vegetable Association

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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

Enclosed is a revised version of comments submitted on December 22, 1997 for inclusion in the docket. We at United were keen to provide the Food and Drug Administration (FDA), as rapidly as possible, comments to the agency's working draft "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables." We have taken the opportunity since December 22 to modify our comments for the purposes of clarity and emphasis. United intends for the enclosed comments to supersede the earlier draft provided on December 22, 1997 and would appreciate the agency's acceptance of these comments as final.

Thank you for considering our request.

Sincerely,

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

97N-0451

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January 22, 1998

United Fresh Fruit
& Vegetable Association

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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 the Food and Drug Administration's (FDA) November 25 draft "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 the United States Department of Agriculture (USDA) to bring the President's initiative to a successful reality.

The United Fresh Fruit and Vegetable Association (United) is the only national trade organization which represents 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.

We offer our comments on the President's initiative and FDA's guide in two parts: first, we will address broad concerns with the President's initiative and the guide; and second, we will provide recommendations on specific components of the guide.

GENERAL COMMENTS

1. If properly developed and communicated broad industry guidance can address any microbiological risks, making commodity specific guidance unnecessary. Instead of focusing government resources on developing commodity-specific guidance we recommend that the industry and government work in partnership to develop education and outreach programs based on broad FDA guidance. It is under this cooperative framework that government and industry can make a true impact on public health. For further support of this position a copy of a December 30 letter from several produce industry groups to Secretary Glickman and Secretary Shalala is attached.
2. The current pace of the initiative threatens to jeopardize produce industry participation and ignores the complexity of our industry. United urges FDA and USDA to take the necessary time to develop guidance that portrays what is practical, reasonable and based in sound science.
3. Any guidance developed by FDA and USDA for the produce industry must be based on sound science and reasonable information. In it's absence, United believes that through educated hypotheses and common sense there exists a reasonable starting point upon which to base recommendations currently and to allow the evolution of policy as science becomes available.

The industry welcomes education about any risks associated with agricultural and handling practices, and is quick to adjust when science warrants. However, epidemiological evidence indicating an emerging food safety issue has greatly preceded scientific information about it's cause or prevention, leaving an industry with limited capacity to respond. To overcome this limitation we believe that the short-term focus should be on education using a common sense approach which is based on broad FDA guidance.

4. United encourages FDA and USDA to rely on principles outlined in the National Advisory Committee on Micobiological Criteria for Foods' 14 August, 1997 Hazard Analysis Critical Control Point Principles and Application Guidelines to develop recommendations for microbiological testing.¹

¹The use of microbiological testing is seldom an effective means of monitoring steps to prevent or reduce a food safety hazard because of the time required to obtain results. A sampling protocol that is adequate to reliably detect low levels of pathogens is seldom possible because of the large number of samples needed.

5. Through broad guidance and other aspects of the initiative it is imperative that the USDA and FDA 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.
6. Buyers of fresh produce will use FDA's guidance as a standard on which to base their purchasing agreements, making it de-facto regulation. United urges FDA to recognize this in moving forward and insure that sufficient language is included to minimize misinterpretation of any recommendations.
7. The import component of the initiative must be developed 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.
8. Guidance must take into account any state, regional, and local regulations currently in place. Industry representatives at every grassroots meeting conveyed that water use, manure and biosolids use, and wildlife are subject to extensive local regulations. Water use is restricted in every region, including what water source an industry operator can use, how much, and when. Federal EPA's standards for the use or disposal of sewage sludge biosolids promotes their use for "maintaining or improving environmental quality and protecting public health." In some regions wildlife management agencies have strict provisions that make it impossible to restrict wildlife movement.
9. Guidance is preferred over regulation because it affords the industry and the FDA flexibility. Given the lack of concrete information upon which to base recommendations and the complexity and diversity of the industry, guidance is an appropriate response. Also, guidance, not regulation, will have the flexibility to accommodate the necessary science, as it becomes available.
10. 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 FDA and USDA to capitalize on our offer to coordinate tours to gain a firsthand view of our industry.

11. Measures to permit rapid approvals for new technologies and new uses of existing technologies should be identified and implemented. FDA and the Environmental Protection Agency (EPA) should review their approval processes for new technologies and new uses of existing technologies, such as ozonation, chlorine dioxide, and irradiation, that address public health concerns associated with fresh produce.
12. Through properly developed guidance on good agricultural practices (GAP's) and good handling practices (GHP's) focused on prevention, microbiological safety concerns in the growing and handling of produce can be minimized. United believes that a Hazard Analysis and Critical Control Point program is not an appropriate regulatory response because the scientific understanding of what gives rise to contamination of produce is very limited.

SPECIFIC COMMENTS

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 guidance is intended to be non-binding. 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, United recommends that industry and government work in partnership to develop education and outreach programs based on broad FDA guidance. Together, within a cooperative framework, government and industry can make a true impact on public health.

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 treatment, not human waste, that is used for fertilizing.

II. Water

Section A. Microbial Hazard, Page 8:

The epidemiological investigation of the *Salmonella* outbreak, originating in Florida, 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 contamination².

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

²Christopher Drew and Pam Belluck, “Deadly Bacteria a New Threat to Fruit and Produce in U.S.,” New York Times 4 January 1998: A1.

influenced by the source and method of irrigation employed. To prevent contamination, water used for irrigation should be of appropriate quality."

United supports the use of the terms "appropriate quality" and "safe for intended use." These terms serve to (1) suggest that water quality is important and (3) provide the industry flexibility to assess appropriate water quality for their individual operations.

Section 1.0 Agricultural Water, Page 10:

Relying upon the testing of water sources to determine if "safe for intended use" is an inappropriate safety management system due to the high probability of nondetection³. 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, microbiological testing of water sources to assure "sufficient quality" should not be a requirement and burden placed on individual operators.

Irrigation water supplies in many parts of the country are strictly regulated. These public authorities should have the responsibility of assuring water quality not individual operators. A number of factors can contribute to water source contamination, so it is unreasonable to expect individual operators to assume 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 omission of the recommendation to use "alternative application methods that reduce or avoid water-to-produce contact" as a mitigation step to ensure that water quality is sufficient for its intended use.

³Dr. J. Madden, "Fresh-cut Ready to Eat Produce - Microbiological Profiles and Pathogens of Concern" presented at the United States Department of Agriculture's meeting on "Research Needs for the Microbiological Safety of Fresh Fruits and Juices," 17 March, 1997, Wyndmoor, PA.

We suggest omitting the recommendation to use "alternative water supplies" as a control mechanism. 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" as a mitigation step to ensure risks are minimized.

There is no room to maneuver when a crop needs water. While the guide 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.

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 conflict with environmental regulations and environmental goals.
- 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 . Thus, under the proposed guidance a 115° F wash bath temperature would be necessary which would damage the fruit and obviously prohibit the removal of field heat.

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 Sludge⁴

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.

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.

United 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, FDA should not recommend current industry practices as policy without first evaluating whether or not they result in minimizing risk.

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" is unwieldy, impractical and has no scientific basis.

Section 3.0 Animal Feces, Page 21:

Produce growers typically seek to exclude high concentrations of wildlife in and around produce fields and orchards because they pose an economic threat. Wildlife management agencies in many regions often 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. Given that intervention is difficult and other agency's conflict with this recommendation, we encourage the FDA to reevaluate this recommendation for it's practicality and real risk in contributing to product contamination.

⁴Municipal biosolids is a more contemporary term and more accurately portrays that it is the by-product of human waste treatment, not human waste, that is used for fertilizing

IV. Sanitation and Hygiene

Section 2.1 Personal Health, Page 22:

Guidance suggests that minimizing risks starts with good sanitation and hygiene practices. Specifically 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" United understands the rationale of these statements but 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, 1997 meeting of the NACMCF, representatives of the Center for Disease Control and Prevention and other public health officials clearly stated that they do not advocate the use of gloves as a substitute for maintaining clean hands. We believe that the same standard should be upheld for crews in the field, packing house operators, inspectors, buyers, and anyone else handling produce. Hand washing, not glove use, should be the recommendation. Promoting one message, without exception, whether a federal recommendation or industry management decision, will result in greater compliance.

Section D. Transportation, Page 30:

United strongly agrees that food safety practices must be continuous from farm-to-table, including the transportation link. The transportation system is a very important link in the food safety chain, and we agree that guidance must address it.

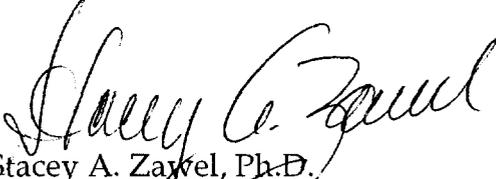
V. Positive Lot Identification

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 identity no benefit will be achieved. Therefore we recommend that this challenge be approached differently. We encourage FDA and USDA to take advantage of the work that the industry, along with its distribution partners, has already begun. If the inclination still exists to develop federal recommendations then United welcomes the FDA and USDA to provide the leadership and a commitment to work in partnership with all segments of the production and distribution chain to effectively address this challenge.

United appreciates the opportunity to provide comment on the President's initiative and look forward to working with you towards our common goal -- to ensure our food supply remains the safest in the world.

Respectfully submitted,



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

December 30, 1997

The Honorable Dan Glickman
Secretary of Agriculture
U.S. Department of Agriculture
14th Street and Independence Avenue, S.W.
Washington, D.C. 20250

The Honorable Donna Shalala
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Glickman and Secretary Shalala:

We, the undersigned organizations, share the goal of the President's initiative to provide for a safe and abundant supply of fresh fruits and vegetables.

Through increased research and efforts to educate people along the farm to table pathway, we believe the President's initiative can benefit the nation's consumers and those who grow, ship and handle produce. All of our organizations have taken steps to identify the key microbiological risk issues relevant to our respective members and the appropriate responses to minimize these risks. We appreciate the opportunity provided to our organizations to participate in and comment on the development of the President's initiative. If the initiative moves ahead based upon sound science and in a deliberate fashion, avoiding unnecessary haste, then we believe the initiative can complement industry's efforts.

Unfortunately, several aspects of the Food and Drug Administration's working draft produce guidance document (dated November 25, 1997) cause us concern. Among the undersigned there exists a range of views as to the effectiveness and public health value of some portions of the draft FDA guidance document. We want to work closely with your respective departments to develop guidance that is both effective and meaningful. Clearly, any guidance which imposes burdens upon the industry and raises the cost of fruits and vegetables without providing distinct public health benefits cannot be considered a success.

In addition, after hearing comments during the regional grassroots meetings, and based upon conversations with Administration officials, we have determined that we must oppose the development of commodity specific guidance. Prescriptive

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guidance on how to grow, handle and distribute specific produce commodities would be impractical to develop and counterproductive. We would anticipate that properly constructed broad industry guidance would identify significant risk factors that may give rise to microbiological hazards in produce and provide growers, shippers and handlers a menu of possible responses to address those hazards, where likely to occur. Devising commodity specific guidance is one option, but we believe this option is fraught with problems and ill considered.

We know of no significant microbiological food safety issues that cannot be properly addressed through a broad industry guidance document and which must be addressed through commodity specific guidance. Moreover, changes in produce growing, harvesting and handling practices are highly dynamic and happen in response to a complex web of interaction occurring among industry operators, government and university researchers, and as a result of innovations introduced by those who provide services and supplies to our industry. We are skeptical that FDA (or any other institution) has the requisite expertise to develop and properly maintain commodity specific guidance intended to apply to many different areas of the country and a wide variety of conditions.

Success in rendering broad industry guidance meaningful at a commodity specific level hinges upon involving people who are credible, knowledgeable and sensitive to the needs of and conditions affecting growers, shippers and handlers. Accordingly, we encourage you to devise a program of education outreach and research founded at the regional, state and local levels. Through the appropriate allocation of resources, the President's initiative can provide focused attention to specific commodities by placing a broad guidance document into the hands of experts and extension personnel working at the regional, state and local levels. A ready universe of experts in the production and handling of commodities reside throughout the Land Grant University system, within state and local governments, and in private sector consulting firms. Also, as you develop and implement the President's initiative recognize that our respective members must comply with a myriad of competing federal and state regulatory requirements: minimizing conflict between these requirements should be a chief goal.

Finally, each of our organizations has worked hard to sensitize and educate our respective members on microbiological food safety issues. We have been pleased by the very interested and eager response of our members who want to minimize microbiological risks. We intend to continue these efforts. Thus, we would welcome

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the opportunity to forge a government-industry partnership to craft a strong, highly visible program of education to promote the continued production, distribution and consumption of safe and nutritious fresh fruits and vegetables.

Thank you for considering our views.

Sincerely,



Thomas E. Stenzel
United Fresh Fruit & Vegetable Association



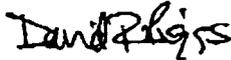
Joel Nelsen
California Citrus Mutual



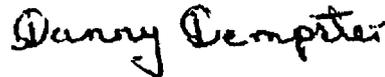
Paul B. Engler
California Citrus Quality Council



Richard Matoian
California Grape & Tree Fruit League



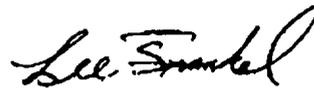
David R. Riggs
California Strawberry Commission



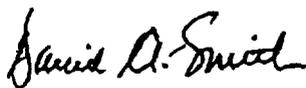
Danny Dempster
The Canadian Horticultural Council /
The Canadian Produce Marketing
Association



Richard Kinney
Florida Citrus Packers



Lee Frankel
Fresh Produce Association of the Americas



David A. Smith
Idaho Grower Shippers Association



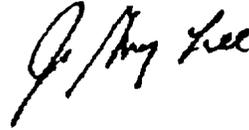
Edith H. Garrett
International Fresh-cut Produce Association

December 30, 1997

Page 4



Vern F. Highley
National Watermelon Association, Inc.



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North American Perishable Agricultural
Receivers (NAPAR)



Bryan Silbermann
Produce Marketing Association



Bill E. Weeks
Texas Produce Association



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Western Growers Association

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Department of Agriculture

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Dr. Michael A. Friedman
Lead Deputy Commissioner
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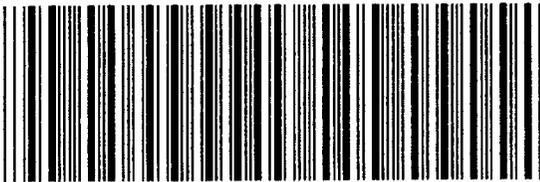
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