

Chairman of the Board  
**David Eldredge**  
Tanimura & Antle

Chairman-Elect  
**Grant M. Hunt**  
Grant J. Hunt Co.

Secretary/Treasurer  
**Ted Campbell**  
SUPERVALU INC.



**Produce Marketing Association**  
*Advancing the Produce and Floral Industries*

1500 Casho Mill Road, PO Box 6036  
Newark, DE 19714-6036, USA

Phone: 302-738-7100 Fax: 302-731-2409  
<http://www.pma.com>

1416 '98 JUL -2 A9-47



June 25, 1998

Chairman of the Executive Committee  
**Robert DiPiazza**  
Dominick's Finer Foods Inc.

Chairman, Retail Division  
**Bruce Peterson, Jr.**  
Wal-Mart Supercenters

Chairman, Foodservice Division  
**Roger A. Askey**  
Bob Evans Farms

Chairman, Floral Marketing Association  
**Kerry L. Herndon**  
Kerry's Bromeliad Nursery, Inc.

President  
**Bryan E. Silbermann, CAE**  
Produce Marketing Association

**Stephen J. Barnard**  
Mission Produce, Inc.

**Dwight Ferguson**  
Florimex North America

**Carl Fields**  
Monterey Mushrooms, Inc.

**Stephen J. Gallucci**  
Wegmans Food & Pharmacy, Inc.

**John G. Giumarra**  
Giumarra Vineyards

**Mike Hamblton**  
Stemilt Growers, Inc.

**Bruce Knobloch**  
Schnuck Markets, Inc.

**Dale Liefer**  
Westlake-Miller, Inc.

**David E. Mixon, Jr.**  
DNE World Fruit Sales

**Claude Moldenhauer**  
The Kroger Company

**Victor Moller**  
HORTIFRUT S.A.

**Jay Pack**  
Standard Fruit & Vegetable

**Mike Rempe**  
C. H. Robinson Company

**Debby Robinson**  
Randall's Food Markets, Inc.

**Roger Schroeder**  
Hughes Markets

**Martha L. Spezia**  
Lettuce Entertain You

**Floyd Warner**  
Ben E. Keith Foods

**Chip Wiechec**  
Hunter Brothers, Inc.

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

**Re: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Docket number 97N-0451**

The Produce Marketing Association is pleased to submit these comments in response to the Food and Drug Administration's request for comments on its proposed Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.

PMA is the largest worldwide not-for-profit trade association representing companies that market fresh fruits and vegetables. Our membership of more than 2,500 ranges from supermarket retailers to grower-shippers, and from hotel and restaurant chains to overseas importers.

Within the United States, PMA's members handle more than 90% of fresh produce sold at consumer level. The association's mission is to create a favorable, responsible environment that advances the marketing of produce and floral products and services for North American buyers and sellers and their international partners. Food safety is a top priority for the association and its members, as it is for FDA.

We applaud the agency for noting that the United States has the safest food supply in the world and for stressing the importance of five servings of fruits and vegetables a day as an critical component of a healthful diet.

We also appreciate the agency's attention to and incorporation of ideas/concepts contained in the produce industry's "Industrywide Guidance to Minimize Microbiological Food Safety Risks for Produce." PMA was a member of the coalition that prepared that document in 1997 because we believe in being proactive about food safety practices and education. We offer our members additional information and training materials on food safety.

Although the risk of foodborne illness from fresh produce is very low, it a risk that we must continually address at all levels – industry, government, and consumers.

97N-045-1



Your Competitive Edge

D  
C 89

In general, the draft proposal for these guidelines is good, especially where it mirrors the industry's own guidelines. There are a few specific concerns, however, on which we would like to comment.

In the Introduction, FDA states: "...some data suggest that the proportion of outbreaks associated with fresh produce compared to other foods may be increasing. Estimates of the incidence and prevalence of foodborne infection from fresh produce are unavailable."

FDA should avoid reference to uncertain, unproven, or unscientific conclusions in this document. While some data may indicate that actual outbreaks are increasing, others believe increased reporting is responsible for the trend. And if estimates of incidence and prevalence of infection from produce are unavailable, how can any conclusions be drawn?

Later, in Section IIA (Water, Microbial Hazard), the agency cites an outbreak of *E. coli* O157-H7 linked to leaf lettuce. "While it is not known where the lettuce became contaminated, investigators noted that the lettuce was irrigated with surface water, which may be vulnerable to contamination..." Such speculation is uncalled for. If it is unknown where the lettuce became contaminated, then it is unknown. There are other examples throughout the document where the contamination vehicle is speculation rather than fact, and they should be avoided as well.

In section 2.2 (Wash water), you ask the industry to consider washing produce in hot water or water containing a surfactant or wetting agent, when washing again or rinsing with clean water. What research or scientific basis is there for this recommendation? Hot water is often inappropriate for many fresh produce items, which generally are kept cool or cold. Have surfactants or wetting agents proven to decrease microbial adherence to fresh fruits and vegetables compared to water alone?

In your discussion of sanitizers or antimicrobials in wash water, emphasis on chlorine as a specific agent may be overstated. Other treatments such as ozone and organic acids are being used effectively in many water sanitizing applications. PMA hopes FDA will encourage industry to use the best options available for water sanitation rather than emphasizing one option.

In the same section, FDA writes of alternative treatments for water-sensitive products, noting that several disinfectant treatments are under study. Low-dose ionizing radiation is mentioned as one of the treatments under study. That option already has been approved by the federal government for use on fruits and vegetables.

In Section IV (Sanitation and Hygiene), A (Worker), FDA advised that "any worker diagnosed with an active case of illness...should be excused from work assignments that involve contact..." This is an excellent recommendation, provided FDA expects the burden of disclosure to be on the employee, not the supervisor or employer. Supervisors are unlikely to be able to tell whether an employee has a diarrheal disease unless the employee makes it known.

Further in Section IV, C (Field), general harvest considerations, FDA mentions raspberries specifically: "Clean and sanitize containers used for ready-to-eat produce, such as raspberries." This is unnecessary as the sentence is perfectly clear without the reference to raspberries.

The same is true in the next part of section IV, D (Packing Facility), under the bullet about cleaning muddy containers. It is unnecessary to mention a specific produce item there.

On the issue of tracebacks, PMA also believes it is important to be able to trace produce back to the source, and we continue to work with industry and FDA on this issue. The vast number of links in the produce distribution chain makes this laudable task very daunting. In fact, it is the complex distribution system more so than the size of any individual operation that complicates this issue. (Later in the document, FDA states that traceback may be easier for larger operations than for smaller ones.)

In the traceback section, FDA talks about challenges facing the produce industry and mentioned lack of traceback can cause false associations, which can hurt industry. The draft mentions that in 1996, the cyclospora outbreak was erroneously linked to fresh strawberries. However, our understanding is that erroneous link was due to epidemiology identifying strawberries as the culprit, not due to the lack of a traceback system.

In the paragraph "Advantages of an effective traceback system," FDA notes that "despite the best efforts by food industry operators, food **may** never be completely free of microbial hazards." In fact, food **can** never be completely free of microbial hazards because we do not live in a microbe-free world. Our best approach is contained in the title of this document – "minimizing microbial hazards."

PMA appreciates the opportunity to present these comments. We applaud the agency for its thorough review of this and other food issues. Please do not hesitate to call upon us if we can be of further assistance. We look forward to working with you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bryan Silberman", with a long horizontal flourish extending to the right.

Bryan Silberman, CAE  
President  
Produce Marketing Association

Align top of FedEx PowerShip Label here.

PRODUCE MARKETING ASSOCIATI

SHIP DATE: 25JUN98  
ACC# 019157423

1500 CASHO MILL RD.  
NEWARK DE 19711  
(302)738-7100

ACTUAL WGT: 1 LBS MAN-WT

TO: DOCKETS MANAGEMENT BRANCH HFA-305 (202)205-5916  
FOOD AND DRUG ADMINISTRATION  
12420 PARKLAWN DRIVE ROOM 1-23

ROCKVILLE MD 20857

4165 6155 5381



REF: 2310

STANDARD OVERNIGHT FRI.:

CAD# 0040903 25JUN98

FEDEX LETTER Deliver by:

TRK# 4165 6155 5381 Form 0201

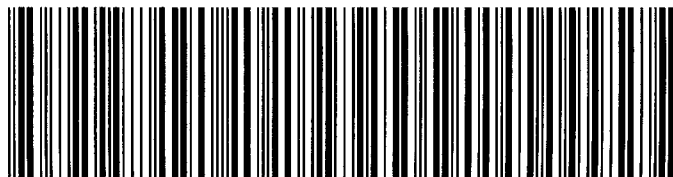
26JUN98

IAD AA

20857 -MD-US

ZM GAIA

153077-077 RIT 3/98



*old* ~~NEWARK DE 19711~~