



Fresh Vegetables, Inc.

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June 25, 1998

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

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SUBJECT: {Docket No. 97N-0451}
Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Federal Register, April 13, 1998.

Dear Sir or Madam:

Dole Fresh Vegetables Inc., submits the following comments on the docket referenced above.

The draft "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" published on April 13, 1998, has addressed many of the concerns expressed by members of the agricultural and food processing communities during town meetings and general comment period subsequent to the first draft published November 25, 1997.

Our comments are limited to the following sections of the proposed draft guide: General, Definitions, Water, Manure and Municipal Biosolids, Sanitation and Hygiene, Transportation and Traceback.

GENERAL: The agencies admit that the incidence and prevalence of food borne infection from fresh produce are unavailable. The agencies also refer to the lack of, or missing pieces of information in the scientific basis for reducing or eliminating pathogens in agricultural settings. In light of this missing information programs should be developed to allow the agencies measure the impact or usefulness of the guide.

DEFINITIONS: The document defines facility as: "the sites and buildings used for, or in connection with, the harvesting, storage, processing, packaging, labeling, or holding of fruits and vegetables". The guide recommends that the facilities should be kept clean and references cGMPs' (Title 21 CFR 110.35 and 110.37) for sanitation. Generally the site used for, or in connection with, harvesting of vegetables and fruits are crop lands and sanitation of the facility as

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referenced in cGMPs cannot be implemented. Not all cGMP guidelines can be followed in the field, but where appropriate they should be employed.

Food contact surfaces are defined as: "those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. Food contact surfaces include equipment used in agricultural practices". The guide recommends that food contact surfaces be cleaned and sanitized periodically. *However*, in the context of the agricultural tools and equipment used in the harvesting of crops, the usefulness of cleaning and sanitizing the equipment is questionable. Some of the equipment used in harvesting operations (depending on the crop and the season) will come in contact with the soil. Sanitizing the equipment in those circumstances will not improve the food safety of the products harvested. The equipment and tools used for such practices are traditionally not designed and constructed of materials that can tolerate a chemical treatment that delivers a 5 log reduction in bacterial counts.

WATER: When water used for agricultural purposes comes from public agencies in the U.S, information on the microbiological quality of the water is available and additional testing should not be necessary. However, when information on the quality of the water is not available, appropriate testing or knowledge should be used to prevent avoidable or known hazards. While drip irrigation does reduce the risk of potential contamination from irrigation water, it is not suitable for all applications and may be cost prohibitive. The guide recommends that water used for irrigation should be protected from uncontrolled livestock or wildlife. Wild life control on the farms is a sensitive issue. The endangered species act and other regulations limit the choices growers have in controlling and limiting wild life access to crop lands.

The guide suggests that washing with hot water should be considered to minimize the chances of internalization of surface contaminants for certain products. The intent of using water in many of these applications is to cool the product by removing as much field heat as possible without damaging the product. While it is important to minimize the chances of microbiological contamination and cross-contamination during these processes, using hot water will not accomplish the primary objective of this operation, which is to cool the product. More importantly, the water used for these applications should be

pathogen free to reduce opportunities for contamination and cross-contamination. The use of warm water may minimize the chances of internalization of *Salmonella* (and other pathogens), but does not prevent from contaminating and cross-contaminating the produce when such pathogens are already present in the warm water.

The guide suggests that produce should be washed and recommends that sanitizers or antimicrobials be used in the wash water. The produce destined for market to be sold as a commodity item is not generally subjected to any wash steps. The water used is primarily to cool the product and to extend the usable life of the product. Even when sanitizers or antimicrobials are used in the water for cooling the product, the intent is to minimize opportunities for cross-contamination of the product and not to sanitize or wash the product.

In the document, a reference was made to an outbreak of *Shigella sonnei* foodborne infection associated with iceberg lettuce, believed to have resulted from the use of contaminated water either for irrigation or cooling after packing. In the United States, iceberg lettuce is vacuum cooled, a process that does not use water to cool the product.

MANURE AND MUNICIPAL BIOSOLIDS: The agencies should provide growers and farmers with the best available information on survival of pathogens and means of reducing risks from these pathogens. In those areas where critical information is not available, programs for developing such information must be put in place.

SANITATION AND HYGIENE: In the section on worker hygiene, the guide recommends that a worker diagnosed with cases of *Salmonella*, *Shigella*, *E.coli* O157:H7 or hepatitis A virus be excused from work assignments that involve contact with fresh produce or produce processing equipment. A supervisor, or an employer, will not know whether a particular employee is infected unless the employee willingly shares that information. Employees may not share such information once they realize that it results in loss of wages (in growing and harvesting operations, all work involves direct or indirect contact of produce; an alternate assignment is not a viable option). It is also well established that people may also be transient carriers of such pathogenic organisms without

showing any visible symptoms of infection. Under these difficult circumstances, a clear guidance on identifying employees infected with transmittable diseases would be beneficial to the growers and farmers.

There are concerns about the practicability of handwashing before commencing work. In field agricultural operations involving planting and harvesting activities, employees may some times come in contact with soil (depending on the crops being harvested and the weather conditions). Under these circumstances, handwashing before starting work will not significantly affect the microbiological safety of the produce. However, all employees must wash their hands (with soap and running water) after using toilets to prevent contamination of produce and equipment with microorganisms of human intestinal origin.

The guide recommends that equipment or machinery having contact with fresh produce, not be used for carrying items such as lunches, tools, etc. When harvesting a field, the harvesting crew travels along with the equipment /machinery being used. The crews have their lunch/meals at an appropriate time in the field (that is being harvested). The microbiological risks associated with storing prepared, ready-to-eat lunches on the equipment /machinery that is used for harvesting and transporting operations is minimal in the worst case. We would recommend that specific areas be identified on equipment in the field for the storage of lunches and tools.

TRANSPORTATION: The growers/shippers may not always have control over the transportation of the produce to the retail outlets. Temperature control and delivery of mixed loads of product (with incompatible refrigeration requirements) is not an uncommon practice at the retail/distribution centers. We would recommend that the guidance be directed at all aspects of the food chain to achieve a continuum of safe food handling.

TRACEBACK: The purpose of traceback of a product is to remove the contaminated product from distribution, but is not adequate for identifying specifically the location at which the product was grown or contaminated. Most of the growers and shippers currently have the capability to trace the product as long as the product is in its' original shipping container and not co-mingled during distribution or retail. The use of bar coding and other systems to trace the

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individual components of a shipment throughout the life of the product could involve huge costs (packaging, documentation, record keeping) to the consumer without providing added benefits. However, alternative cost effective and useable systems should be investigated to further improve the traceability of the products.

Thank you for the opportunity to comment on the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. If you have any questions regarding my comments or wish to contact me regarding other concerns, please call. My direct telephone line at Dole Fresh Vegetables is (408) 678-5406.

Sincerely,

DOLE FRESH VEGETABLES, INC.



Mahipal R. Kunduru, Ph.D.
Manager Food Safety

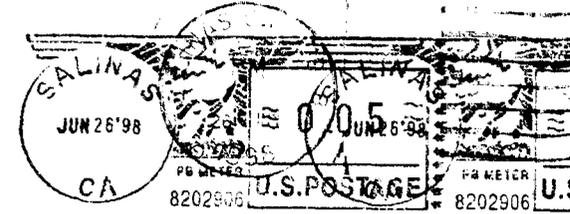
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