



July 23, 2004

Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

RE: Docket No. 2004N-0258, Produce Safety from Production to Consumption, 69 Fed. Reg. 33,393 (June 15, 2004)

Subject: Western Growers Comments on FDA's Proposed Action Plan on Produce Safety

Western Growers is a non profit agricultural trade association representing growers, packers and shippers of fresh fruits nuts and vegetables that are grown packed and shipped in California and Arizona. Western Growers members grow, pack and ship nearly 90% of the fresh fruits, nuts and vegetables in California and approximately 75% of the fruits, nuts and vegetables in Arizona. Combined, Western Growers' over 3000 individual members produce more than 200 different fresh produce commodities accounting for approximately 50% of the total U.S. fruit, nut and vegetable production – which is valued at over \$30 billion.

These member companies place a high priority on the quality and safety of their products and are firmly committed to the continual advancement and implementation of systems and practices that will improve them.

As such, Western Growers is extremely interested in FDA's recently announced proposed "Produce Safety from Production to Consumption: A Proposed Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption". We strongly support FDA's overarching goal of reducing foodborne illness associated with the consumption of fresh produce. We are firmly committed to working closely with FDA on the key objectives of prevention, mitigation, response, communication and research in our collaborative efforts to make the safest fresh fruit and vegetable system in the world even safer.

Western Growers concurs with FDA that this "action plan" requires the active participation of all partners in the academic, public and private sectors and that it will require the cooperation and collaboration of all sectors of the produce industry. Each one of these discrete entities is a critical link in the chain of custody of a product from the field to the fork and our entire system is only as strong as the weakest link. With

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that in mind we appreciate greatly the opportunity to begin a dialogue with FDA and others on these topics and offer the following preliminary comments, guided by the questions offered in the federal register notice.

In addition to these preliminary comments, WG would be supportive of an extension of the comment period in order to get more comprehensive input in the formulation of our responses as well allowing a reasonable amount of time for WG and others to engage the industry at large in a full review of the draft plan. This is a critical issue to the American fresh fruit, nut and vegetable industry and a comment period of slightly more than one month is inadequate to foster collaborative approaches, partnerships and protocols to achieve our mutual goals.

Preliminary Comments:

Western Growers encourages FDA to delineate publicly all objectives in the 2004 Produce Safety Action Plan. Currently we have seen four discrete objectives identified in the documentation released in conjunction with the announcement and call for feedback on the “plan”. These four overarching objectives: 1) to prevent contamination; 2) to minimize the public health impact when contamination occurs; 3) to improve communication and to facilitate and support research are laudable objectives that we wholeheartedly support and are eager to work with FDA and others to achieve.

As we all agree, the major goal of any collaborative “plan” should be to “minimize foodborne illness associated with the consumption of fresh produce”. Western Growers also agrees that this will be best achieved through a multifaceted approach requiring efforts, resources and collaboration between food safety partners from the public and private sectors. We are strongly committed to working both independently and collaboratively to ensure the safety of fresh fruits, nuts and vegetables.

While each objective is important in its own right, Western Growers believes there is a natural progression that should dictate how elements of the “plan” are pursued. For example: research is a necessary first step in identifying where to devote our highest levels of energy and effort. WG has said in many public forums that it is imperative that we understand for example the breadth and scope of GAP implementation throughout the fresh produce industry. “Are the outbreaks of foodborne illness that have been associated with fresh produce related to failure of current GAPs....are they related operations that do not employ GAPsAre they the result of non-compliance with GAPs”.....?? These are fundamental questions that will direct follow-up efforts. The answers determine whether we focus on specific GAPs and the development perhaps of commodity specific guidance or whether it is more appropriate to focus on broadening the implementation of GAP use and monitoring systems. These questions relate directly to FDA’s stated strategy of identifying research that is likely to make the most significant contribution to reducing the public health risk from contaminated fresh produce.

While FDA is appropriately encouraging all sectors of the production and distribution chain to embrace and collaborate on the “plan” there is and has been an emphasized focus on the production sector. Several of the itemized strategies that FDA is recommending exclusively highlight the production sector. Key among these are those recommendations for sampling improvements directed towards producers. This focus may indeed make sense in the context of “potential” risk since product is often rapidly distributed to multiple locations but this “potential” risk and corresponding attention does not correlate with data gathered by FDA, CDC and others. In fact this data demonstrates only a small percentage of historical outbreaks are actually attributable to failure at the producer level. In fact, a much higher percentage occur up-stream from the producer, processor or shipper. Appropriate research, using historical and emerging data, should be conducted to determine where to appropriately focus efforts within the entire distribution chain. This includes the development and implementation of appropriate sampling methods upstream from producers.

That said, producers recognize that “potential” risk should be minimized. We currently focus much of our research funding in areas that will assist in eliminating or minimizing the potential for contamination through the implementation of GAPs, GMPs and other business and production practices that promote food safety. Western Growers is supportive of research in a number of areas related to fresh produce production and handling in an effort to help gain a better basic understanding of how human pathogens and produce interact

There are several key areas of needed research that include 1) microbial ecology of human pathogens in the agricultural production environment; 2) agricultural water (irrigation as well as packing and processing waters), 3) rapid detection methods for potential pathogens; 4) soil amendments; 5) proximity to potential contaminant sources and 6) intervention strategies to reduce the risk of human pathogens contaminating fresh produce.

Reducing the incidence of foodborne illness in produce requires an integrated and well funded research effort that encompasses all facets of the production, processing, transportation, distribution and sales chain. It is important that investments made in conjunction with the “plan” be grounded in hard science that provides clear evidence that food safety will be enhanced rather than unproven actions that take limited food safety resources away from addressing real risk.

While effective research allocation and strategy takes an up-front role in the development, refinement and implementation of an effective “plan” so does education and communication. Western Growers believes that the FDA’s Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (or comparable guidance) should be more strongly promoted. In addition similar “guidance” for other component parts of the production and distribution chain (transportation, food service, retail, consumer etc.) should likewise be aggressively promoted. In cases where research identifies a need, additional guidance should be developed. This may include,

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commodity-specific or general guidance, applicable to the production of fresh produce as well as to its handling transportation, storage, and retail marketing and consumer safety.

In addition to education Western Growers believes that to best serve the overarching public health goals of the FDA, it is imperative that the FDA improve communications with all the partners in the fresh produce industry. This is an extreme challenge because the fresh produce industry is characterized by an immense diversity of products, producers, and regions all of which are combined with an extremely broad spectrum of customers throughout the country. FDA must make an effort to have more direct contact with the regional produce associations, commodity boards or specialty produce trade associations. These organizations are most capable of actively reflecting current industry practices and can facilitate the most direct communication between growers, packers and shippers and the agency.

In addition, the agency must also develop communications protocols that inform consumers quickly of potential foodborne illness outbreaks without unnecessarily scaring them from the consumption of commodities known to be safe. FDA must again collaborate with commodity organizations to insure the information is timely and that it effectively warns the public without endangering the industry. This is a delicate balance, and Western Growers agrees that it is prudent to err on the side of public caution. In these instances we strongly encourage FDA to continue to develop follow-up information that can be shared with the public when the concern has been mitigated. Western Growers strongly encourages FDA to release their proposal for communications protocols and to work withal parties to develop a sound communications policy.

The strategies identified in the plan in which FDA would “establish a protocol to ensure that consumers are informed as quickly as possible about a foodborne illness outbreak involving an FDA-regulated product as well as mechanisms to ensure prompt communication between federal, state, and local food safety agencies and foreign governments should be carefully coordinated with the private sector when there is a concern about a particular region, practice, or commodity. Communicating with the potential impacted parties in a manner that does not compromise FDA integrity but also allows for discussions about appropriate messages and the minimization of “collateral damage” often caused through FDA communications must be a key effort in developing the “plan”. In addition, Western Growers supports FDA efforts to raise and maintain consumer awareness about how to handle fresh produce safely and to utilize the internet to promote ready access to educational materials for fresh produce producers, distributors, retailers, food workers, and consumers.

The FDA proposal to develop commodity-specific handling advice must be done in close collaboration with the key representatives of the commodity including principally the local or regional producers and academia. Commodity specific handling advice that would be disseminated from FDA to state and local food safety agencies for

communication to preparers of fresh produce such as retailers, restaurants, and food service operations can raise potential adverse perception issues and corresponding market impacts. These types of communication efforts must be closely coordinated with stakeholders.

The current draft produce safety action plan's strategy of expanded surveillance of fresh produce for the presence of human pathogens as a means of minimizing public health impacts must be examined. While we agree that the speed and accuracy of tracebacks, the preparation and training of inspectors and the further coordination of existing systems employed by FDA, state and local agencies are all part of an integrated approach to minimizing the impact on public health when outbreaks occur we remain unconvinced that increased sampling and monitoring are the most effective uses of limited resources when attempting to respond to outbreaks. Enhanced sampling and better detection methods may not best advance the stated goal of reducing foodborne illnesses associated with produce. Western Growers believes that this is a prime example of how research that is grounded in hard science must precede the development and implementation of new sampling regimes, lower detection levels, broader surveys and other elements that may make up "expanded surveillance". There must be clear scientific agreement on what are the appropriate indicators of contamination, where are the appropriate sampling points, what levels of detection constitute risk and why and a host of other questions for which there is not ready agreement today. Before we place an emphasis on the premise that we can sample our way to a safer food supply we must insure that we are looking for the right things in the right places at the right levels and the appropriate times. Enhanced surveillance without sound scientific basis underlying it will only serve to take valuable and limited resources away from prevention, research, education, and communication objectives that may prove more effective in reducing the number of outbreaks of foodborne illness associated with fresh produce.

Western Growers is appreciative of this opportunity to comment on the Produce Safety Action Plan. Our industry and Association have made food safety our number one priority and we remain committed to providing a safe, high quality supply of fresh produce both domestically and abroad. Western Growers is additionally committed to taking a lead role in enhancing the safety of products delivered to the market by our members and others and developing proactive approaches in collaboration with FDA and others to achieve the common goal of minimizing food borne illness associated with fresh produce. We look forward to continuing to work together with FDA on these important matters and look forward to the submission of additional comments as we drill down on strategies within the Produce Safety Action Plan.

I am pleased to answer any questions or concerns relative to these comments or any other issue involving Western Growers activities and efforts supporting food safety.

Sincerely,

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