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Food and Drug Administration  
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Room 1061, HFA-305  
Rockville, MD 20852

United Fresh Fruit  
& Vegetable Association

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Dear Sir/Madam:

The United Fresh Fruit & Vegetable Association is pleased to provide comments on the Food and Drug Administration's guidance documents and specific questions contained in Docket Number O1D-0583 67 Federal Register 1224. United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States.

We commend the FDA for its leadership in working with the private sector, including our industry, to ensure that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. The guidance documents published by FDA offer generally wise advice to industry, and a clear sense of the scrutiny all food producers and handlers must apply to our systems for food security.

The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of public health, and that risk management steps are properly weighed with the public health impact on the cost and availability of fresh produce.

The produce industry strongly supports guidance based on sound scientific results that can help the industry enhance the safety and security of produce, enhance consumer confidence, and increase the consumption of fresh fruits and vegetables.

Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

Sincerely,

Donna M. Garren, Ph.D.

Vice President, Scientific and Technical Affairs

O1D-0583

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United Fresh Fruit  
& Vegetable Association

**Comments on Docket Number O1D-0583  
67 Federal Register 1224**

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The terrorist attacks of September 11, 2001 have had a dramatic impact on almost every aspect of American life. In addition to the devastating human toll caused by the attacks themselves, the fear of future terrorist incidents has undermined the individual sense of safety and security that many Americans long have taken for granted. The financial fallout also has been severe and has resulted in increased pressure on the economy and risk to private enterprise from both real and imagined threats.

The dramatic impact of these events has led to a new focus in public policy aimed at promoting greater safety and security and preventing terrorist action. As our members provide over 1,000 different fresh fruits and vegetables to American consumers from both domestic growers and around the world, we take seriously our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products.

We commend the FDA for its leadership in working with the private sector, including our industry, to ensure that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. The guidance documents published by FDA offer generally wise advice to industry, and a clear sense of the scrutiny all food producers and handlers must apply to our systems for food security.

However, we must continue to stress that industry and government efforts can only reduce the risk of intentional contamination, not eliminate all risk. In any risk management system, one reaches a point of diminishing returns in reducing risk, versus increasing costs or taking steps unacceptable to society at large. For example, grounding all commercial aircraft after the 9-11 attacks virtually eliminated the risk that such aircraft could be used as missiles in an attack. Yet, society has chosen more appropriate risk mitigation steps such as careful passenger screening and bolted cockpit doors.

In this regard, we comment first on FDA's two questions raised in the Federal Register.

**The Use of Tamper-Evident Packaging**

As an industry that markets highly perishable and living, breathing products, tamper-evident packaging would not be feasible for the vast majority of produce products available in the marketplace. Tamper-evident packaging would also dramatically alter how consumers select produce, which remains a sensory experience of touch and smell. The fresh fruit and vegetable industry and the retail supermarket industry have found that bulk fresh produce displays are an

integral component in helping consumers choose sufficient produce items to fulfill 5 A Day health and nutrition goals.

Today, many produce items are being offered in convenience packaging, such as salads in a bag or pre-cut small vegetables. Cut fruits are also being offered in plastic cups or other molded packaging. For these products, the packaging is intended for the consumer's convenience and is uniquely designed to meet the quality control needs of the fruit or vegetable it contains. The design of current packaging materials for fresh fruits and vegetables allows for proper cooling, ventilation, and product integrity, but cannot be considered tamper-evident packaging. The unique shape, size and form in which fresh produce comes does not lend itself to tamper evident packaging. More importantly fresh produce is a living product with various respiration rates that would require various types of packaging materials. Confining the respiratory gases within the package can have a very negative impact upon produce quality. More importantly it could also have a very negative affect on the product safety. Current packaging technology does not afford any enhancements that the product does not currently have in its natural form.

For foodservice applications, such as salad bars in either restaurants or grocery stores, tamper-evident packaging is clearly not feasible. Fundamentally, as fresh fruits and vegetables are marketed directly to consumers at retail and restaurant level, the industry and government must recognize that requiring tamper-evident packaging would be commensurate with grounding commercial aircraft. It would have significant impact on the *fresh* produce business. Rather, the produce industry and our retail partners will continue to increase our vigilance and risk mitigation systems to prevent isolated tampering incidents at retail level.

#### **The Use of Procedures and Records for Traceback-Traceforward**

With highly perishable products that move quickly through distribution systems and are consumed quickly, the fresh produce industry believes government's most important investment in either food safety or food security is in *prevention*, not tracking records after the fact. Unlike many processed food products, a certain lot of fresh produce is likely gone from the food distribution pipeline before public health authorities even learn of an illness to start a traceback investigation.

We believe current carton or bulk package labeling which contains the name and address of the food marketer is effective in allowing investigators to identify the sources of the product, and then look into the general agricultural and handling *practices* of the grower-shipper to further enhance *prevention* should systemic problems be identified. In the potential case of intentional contamination occurring at the producer level, if such tampering is not caught through the distribution chain until a consumer is affected, such carton labeling could still quickly identify the source of the product.

Some produce and retail companies are adopting various case or pallet coding schemes to allow tracking of product movement for logistics efficiency. However, such logistics systems are not intended to scan and permanently record all data at every stage of a product's movement in order to facilitate a computer search of records to identify the pathway of the product some weeks later. These systems are designed for warehousing, restocking and ordering efficiency, not food security. Tracking and storing the huge volumes of information that FDA contemplates would be a massive imposition of costs and operational burden for industry, with little real benefit in food security or food safety. We ask the agency to refocus its efforts on true risk mitigation –

how can industry and government collectively prevent intentional acts of terrorism that result in food contamination? That must be our supreme goal.

### **General Guidance**

As for the general guidance documents, we applaud FDA's timely and thoughtful advice to the broad food industry on these important issues. We are encouraged that the agency has issued these documents as "Level 1" guidance, allowing flexibility for food industry operators to use a "tool box" approach with recommendations that best fit their operations. With the produce industry's diversity of products and complexity of global production and distribution, flexibility is critical in that many prescriptive recommendations would be inappropriate or not applicable to our industry.

Because FDA has issued broad general guidance, rather than regulatory prescription, our industry supports the intent of FDA to stimulate the careful review and assessment of a wide range of security measures. This is precisely the process our organization and our members have undertaken and will continue. However, we have reservations about certain provisions of these documents that are clearly not appropriate for the produce industry, and that, regardless of intentions, could become "de facto" regulation due to market and liability pressures.

Therefore, we want to include for the record some examples of where specific comments are inappropriate for our industry. This is meant for illustrative purposes, and is not comprehensive. Should FDA contemplate proposing new regulations in this regard, United would want the opportunity to comment specifically on the entire slate of recommendations in much more detail.

Specific recommendations that illustrate this point include:

1. Management of food security
  - Supervision: Suggesting that daily security checks of the premises be conducted is too prescriptive, particularly in primary production environments. Firms should determine the frequency of security checks that best suits their own individual needs.
  - Mail/packages: It is not relevant for all segments of the produce industry to visually inspect or x-ray all incoming mail and packages.
2. Physical facility
  - Due to the growing and packing environments, it is inappropriate to suggest that perimeter fencing and metal-clad doors be viable options for securing primary production areas found in the fruit and vegetable industry. Access can be controlled without these specific measures.
3. Employees
  - Pre-hiring screening: While verifying work references, addresses, and phone numbers of new employees are effective screening measures, performing criminal background checks and verifying immigration status beyond that called for in current law could be an enormous cost with little benefit. The produce industry relies heavily on seasonal, temporary, and contract labor and these measures could negatively impact the supply and cost of fresh fruits and vegetables. In addition, many state and local worker privacy laws prohibit such checks.

4. Raw materials and packaging
  - It is inappropriate to suggest that suppliers, transporters, warehouses, and vehicles be *audited* to ensure implementation of food security measures, as there are no government guidelines for such measures and thus no system that address audit standards. In the case of Good Agricultural Practices, our industry has worked closely with FDA to implement, educate and audit to a specific set of practices. The more appropriate advice in food security is that business partners address mutual interests in food security measures with their customers and suppliers.
  
5. Finished products
  - Requesting vehicles, containers, and/or railcars be locked and sealed throughout distribution may appear initially to be sound advice for most manufactured goods. However, due to the perishability of fresh produce and the complexity of the produce distribution chain, this request would present significant challenges to the marketability of fresh fruits and vegetables. For example, a sealed refrigerated truck must still allow air circulation into the interior load for cooling, thus negating the perceived benefit of the door seal.
  
6. Operations
  - Security of water: "To the extent possible" should be applied to the section concerning the security of water sources as well as the air circulation systems. Due to the scarcity of water supplies in many primary production areas across the U.S. and abroad, the security and access of water sources may be out of the control of many producers.

The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of public health, and that risk management steps are properly weighed with the public health impact on the cost and availability of fresh produce.

The produce industry strongly supports guidance based on sound scientific results that can help the industry enhance the safety and security of produce, enhance consumer confidence, and increase the consumption of fresh fruits and vegetables.

Since September, United Fresh Fruit & Vegetable Association and its members have been actively assisting the FDA in better understanding the production, packing, processing and distribution of fresh produce and potential supply chain vulnerabilities. United formed its own Food Security Task Force in September to address food security issues from farm to table and continues to address produce-specific issues for our industry. In the coming months, we also will be joining with the Food Marketing Institute in a new Food Industry Information Sharing and Analysis Center (ISAC) to work with the FBI and other government agencies. The new ISAC will provide information and analysis that will enable the food industry to report, identify and reduce its vulnerabilities to malicious attack, and to recover from any attacks as quickly as possible.

Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

For additional information, please contact:  
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