



Comments on Docket Number 02N-0277

United Fresh Fruit
& Vegetable Association

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The United Fresh Fruit & Vegetable Association is pleased to provide comments on the provisions of Title III, Subtitle A, Section 306 (Establishment and Maintenance of Records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") contained in Docket Number 02N-0277. United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States.

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 U.S. Food and Drug Administration (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. 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.

Let us keep in mind the American food supply continues to be the safest in the world. Continuing to ensure the safety and security of fresh fruits and vegetables whether produced domestically or abroad is a top priority of the entire produce industry. Food security systems should be risk-based and recognize and respond to new risks as they arise, provide the same level of protection to consumers, whether produced domestically or abroad, efficiently steward new technologies to the market, and effectively educate and communicate to stakeholders throughout the supply chain.

With this in mind, we have reservations about certain provisions of Section 306 (Establishment and Maintenance of Records). Therefore, we want to include for the record some recommendations that will assist FDA in the development of new regulations associated with Section 306 of the Bioterrorism Act.

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We encourage FDA to issue regulations that allow flexibility and take into account 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 diverse industry.

While we do not oppose access to certain records when there is a reasonable belief by the Secretary that a food is adulterated or presents a serious adverse health threat. We do, however, believe the government's most important investment in either food safety or food security is in *prevention*, not tracking records after the fact. This is particularly important with highly perishable products that move rapidly through distribution systems and are quickly consumed. 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 a threat or contamination event.

We also caution the Secretary to be absolutely certain that there is strong evidence to support the "reasonable belief" statute because consumers will turn away from a product that is potentially tainted. Generally, an entire commodity segment is damaged during a contamination event and can result in a significant economic loss for the entire industry.

As we have stated, our products are highly perishable and move through the supply chain very quickly in comparison with other food products in the food industry. With this in mind, we have serious reservations about the two-year time period for maintenance of records appears to be arbitrary and excessive.

Also pertinent to the produce industry is the exclusion or exemption of farms from the registration requirement. We commend FDA for putting forth such an exemption; however, there is no clear federal definition of farming operations that would assist FDA in defining the parameters of this exemption.

Historically, farming has played an important role in our development and identity as a nation. The official definition of a farm in the United States is determined by the U.S. Department of Commerce and as might be expected, this definition has a commercial orientation. Variations of this official definition have been around since 1850 when the first census of agriculture was taken. According to U. S. Department of Agriculture's National Agricultural Statistics Service, since 1974, a farm has been defined as "any establishment from which \$1,000 or more of agricultural products were sold or would normally be sold during the year." Generally, FDA has defined exemptions, related to the produce industry, in the Food, Drug, and Cosmetics Act (FD&C Act) based on the definition of a "raw agricultural commodity." According to the FD&C Act, the term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. To assist in defining a farm for the purpose of the Bioterrorism Act, we recommend FDA using the definition of an agricultural operation set forth in the California Agricultural Protection Act:

"For purposes of this section, the term "agricultural activity, operation, or facility, or appurtenances thereof" shall include, but not be limited to, the cultivation and tillage of the soil, dairying, the production, cultivation, growing, and harvesting of any agricultural commodity including timber, viticulture, apiculture, or horticulture, the raising of

livestock, fur bearing animals, fish, or poultry, and any practices performed by a farmer or on a farm as incident to or in conjunction with those farming operations, including preparation for market, delivery to storage or to market, or delivery to carriers for transportation to market.”

Also, we have reservations about the amendment to Section 301 making it a prohibited act to refuse to permit access to or copying of any required record or to fail to establish or maintain any required record. We do not oppose this amendment, but we encourage FDA to communicate clearly to consumers that this is a failure of a food company not to allow access or maintaining appropriate records not because of an inherent food safety or security risk. Lack of adequate communication may result in false food scares and undermine consumer confidence in the agency.

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.

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. The produce industry strongly supports regulations 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.

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